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Supreme Court, U.S.
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No. 10-1292

In The Supreme Court of the United States

DANIEL CHAPTER ONE, a corporation sole, and JAMES FEIJO, individually, and as an officer of Daniel Chapter One,

Petitioners,

v.

FEDERAL TRADE COMMISSION,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The District Of Columbia Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the Federal Trade Commission Act gives the Federal Trade Commission ("FTC") jurisdiction over a church and religious ministry selling herbal and natural dietary products to its parishioners as part of a faith-based program.

2. Whether the FTC may require a church and religious ministry selling herbal and natural dietary products to its parishioners as part of a faith-based program to: (1) support its claims of health benefits with "competent and reliable scientific evidence including clinical trials with human subjects"; or (2) to send its customers a letter with a message attributed to the FTC which contradicts the beliefs of the ministry.

RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 29.6, petitioners state that they have no parent company or nonwholly-owned subsidiaries.

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PETITION FOR A WRIT OF CERTIORARI

OPINIONS BELOW

The opinion of the court of appeals is unreported and is reproduced in the Appendix (App. 1-5). The order denying rehearing en banc is reproduced in the Appendix (App. 345). The modified final order of the FTC, the opinion of the FTC and the initial decision of the Administrative Law Judge ("ALJ") are reproduced in the Appendix (App. 6-17, 18-74, 75-344) respectively.

JURISDICTION

The court of appeals judgment was entered on December 10, 2010. A timely petition for rehearing was denied on February 16, 2011 (App. 345). The jurisdiction of this court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The First Amendment to the United States Constitution provides, in relevant part: "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to

petition the Government for a redress of grievances." U.S. Const. Amend. I.

Sections 4, 5(a), 5(b) and 12 of the Federal Trade Commission Act (15 U.S.C. §§ 44, 45(a), 45(b) and 52) are reproduced in the Appendix (App. 346-361).

The Religious Freedom Restoration Act of 1993 (RFRA), 42 U.S.C. §§ 2000bb *et seq.*, is reproduced in the Appendix (App. 362-366).

STATEMENT OF THE CASE

This case raises important questions relating to the jurisdiction of the FTC, under 15 U.S.C. § 44, to regulate a church which sells dietary products to its parishioners as part of a faith-based healing program.

A. Factual Background

Daniel Chapter One (hereinafter DCO) is a Christian spiritual and physical church and religious ministry. It is formed as a nonprofit corporation "sole" under Washington state law. James Feijo and his wife, Patricia Feijo, founded DCO with a mission of healing based on Biblical scriptures including Genesis 1:29. DCO's mission is inspired by the first chapter of the Book of Daniel (literally, Daniel, Chapter One – it states that "Daniel and men . . . were expected to eat the king's very rich diet . . . , but instead ate and drank only pulse and water." DCO embarked on its ministry based upon the "integration of spiritual and

physical well being." DCO developed its own herbal and natural dietary products, including the products at issue here, known as BioMixx, Bio*Shark, 7 Herb Formula, and GDU. DCO created the website, "www.danielchapterone.com," which was its major means of distributing its dietary supplements (App. 96-99, 212-213).

DCO had a Monday through Friday, two-hour per day radio program, called "Daniel Chapter One Health Watch." Co-hosted by the Feijos, the program offered integrated spiritual and physical counseling on healing and well-being, as well as a toll-free number that people could call to purchase products. The Feijos engaged in religious counseling of persons who called into the radio program, sharing their knowledge of the products, personal testimonies, and the word of God. Listeners to the radio program freely called in and gave religious testimonies as to how their faith in God, their change in diet and their use of dietary supplements had improved their health (App. 115-116, 213).

From 2002 when DCO was formed as a corporation sole, and throughout the period covered by the FTC Complaint, DCO has operated as a church and religious ministry, combining the teaching of Biblical principles of spiritual and physical wellness and the distribution and sales of natural healing products (App. 98-101, 212-213).

In the development of its products, DCO "did not conduct or direct others to conduct," nor were they "aware of," any "scientific testing" of the effects of

such products by means of the kinds of clinical studies required by the FDA for pharmaceutical drugs (App. 178). Such testing is "a particularly challenging and costly endeavor to undertake for testing herbal products, because it is difficult to extract and test a single chemical component from an herb, and because an herb may comprise thousands of chemical components" (App. 188). Instead, DCO "relied upon a variety of materials, books, magazines, and articles . . . which provided them with an understanding of how certain substances in the Four Challenged Products could be utilized to help healing" (App. 179). The products were developed on the Biblical foundation that nutrients extracted from their natural form in God's creation can help trigger the body to heal itself (App. 99, 212). DCO relied upon research, and communicated "personal observations and customer testimonials" to substantiate their curative effects (App. 179).

DCO extended its message of spiritual and physical wellness and products of natural healing through its Internet website, printed publications, personal counseling, radio broadcasts, call center, and stores and distributors. Through these media, DCO presented information about the products and personal testimonies of cancer sufferers who benefitted from one or more of the products (see, e.g., App. 212-213).

There was no representation, express or implied, that any health claim made as to any of the products was backed up by: (1) clinical trials, randomized, controlled, or otherwise; or (2) even by "competent

and reliable scientific evidence." In fact, DCO placed warnings on the Internet, including disclaimers, along with the statements that "[t]he information on this website is[:] [i] intended to provide a record, and testimony about God and His creation, and [ii] designed to support the relationship that exists between a patient/site visitor and his/her health care provider." DCO did not market the products as a drug, let alone, as a new drug. It simply provided the products as a form of faith-based natural healing.

DCO marketed the products by providing personal testimonies witnessing to the effectiveness of those products with the message that each person has the right to choose one's own medical treatment (App. 126-177). DCO provided descriptions of each product, listing its ingredients and specific uses.

B. The Commission's Decision

On September 16, 2008, the FTC issued the Complaint in this matter. The Complaint alleged that DCO and James Feijo engaged in deceptive acts or practices in connection with the advertising, promotion, offering for sale, and distribution of four products: Bio*Shark, 7 Herb Formula, GDU, and BioMixx (collectively, the "Challenged Products"). The Complaint alleged that DCO and Mr. Feijo operated linked web pages on the website, www.danielchapterone.com, through which they advertised and sold the Challenged Products. The Complaint alleged that the Challenged Products were advertised to prevent, treat, or

cure cancer or tumors. The Complaint further alleged that DCO and Mr. Feijo represented, either expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the claims made, but that they did not, in fact, possess and rely upon such reasonable basis. The Complaint charged DCO and Mr. Feijo with unfair or deceptive acts or practices, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act (App. 86-87).

The FTC did not allege that DCO had "falsely touted clinical or scientific proof" for the products at issue. Nevertheless, the FTC sought to prevent DCO from making health-related representations about any products unless DCO "possessed and relied upon competent and reliable scientific evidence," even if the representation would otherwise be "true and non-misleading" (App. 321-322).

On January 25, 2010, after a hearing before an Administrative Law Judge (ALJ), and an appeal to the Commission, the FTC issued its Modified Final Order ("Order") directing DCO to cease and desist from certain specified acts and practices and to perform affirmative acts as directed by the FTC (App. 6-17). From these rulings, DCO appealed to the Commission.

On December 18, 2009, the Commission affirmed, adopting all of the ALJ's findings of fact, as well as the ALJ's specific conclusion that DCO's ads in connection with the Four Challenged Products were misleading because DCO did not possess or rely upon the kind of "controlled clinical studies" necessary for

a new drug to obtain FDA approval. Additionally, the Commission affirmed the ALJ's constitutional rulings, but unlike the ALJ, ruled on and denied DCO's RFRA defense on the merits. The FTC issued its final modified order on January 25, 2010 (App. 6-17).

C. The Court of Appeals Decision

A timely petition for review was filed in the D.C. Circuit Court of Appeals pursuant to 15 U.S.C. § 45. The court of appeals denied the petition for review in an unreported opinion (App. 1-5). The court of appeals held that the Commission properly exercised jurisdiction over DCO and that, contrary to DCO's argument that its status as a church and religious ministry prevents the FTC from regulating its advertisements, the jurisdictional inquiry properly focused on the substance of DCO's activities (App. 2-5).

The court of appeals also found that the Commission did not exceed its statutory authority by requiring DCO to have and rely upon a reasonable basis to substantiate its claims including "competent and reliable scientific evidence" including clinical trials with human subjects (App. 3).

The court of appeals rejected the claim that requiring DCO to send its customers a letter with a message attributed to the FTC which contradicts the beliefs of the ministry violates the Constitution and RFRA (App. 2-5).

REASONS FOR GRANTING THE PETITION

I. The FTC Act Does Not Give the FTC Jurisdiction Over a Church or Religious Ministry

The decision below is the first time in which the court of appeals has held that a church or religious ministry is within the jurisdiction of the FTC under the FTC Act and the first time the court of appeals has held that the jurisdictional inquiry properly focuses on the substance of an entity's activities rather than its corporate form. The FTC itself said, in its Motion to Reconsider Publication of Opinion, that this case was "the first time in which the [court of appeals] has issued a ruling on the contours of the jurisdictional inquiry under the FTC Act" and "the first instance in which this [court of appeals] has held that 'the jurisdictional inquiry properly focuses upon the substance of [an entity's] activities, and not its corporate form.'"

The authority asserted by the FTC for this novel expansion of their jurisdiction, which was adopted by the court of appeals, does not support that conclusion. The FTC and the court of appeals analogized jurisdiction over a trade association in *California Dental Ass'n v. FTC*, 526 U.S. 756 (1999) to jurisdiction over a church or religious ministry that engages in net income-producing activity to fund its ministry. Yet, a religious ministry has never before been treated as a trade organization like an association of local dental societies.

The plain language of 15 U.S.C. § 44 requires more than making a profit. The FTC's jurisdiction is limited to the type of corporation that is "organized to carry on business for its own profit or that of its members." There is no authority for the FTC to exercise jurisdiction over a church or religious ministry. It is unprecedented to treat a church or religious ministry as merely a corporation organized to carry on business for profit.

There was substantial evidence before the Commission that DCO is a church or religious ministry involving many adherents to its religious beliefs. The beliefs of DCO and its members are deep-seated. The court of appeals accepted without discussion the FTC's assertion that DCO was simply the same as a commercial trade association. The court did not address the distinctions between a group of dentists getting together to promote their dental practices and a religious organization.

Many of the major religions of the world involve large corporate structures. It is well known that major religious organizations have been, and, to this day, are major land owners. Churches have had large ownership interests in banks. Some religious leaders have lived exotic lifestyles while many others in religious orders have lived lifestyles well in excess of what James Feijo and his wife have been alleged to have enjoyed. The court of appeals did not address the evidence before the Commission which clearly demonstrated DCO is a church and religious ministry. Instead, the opinion compared this ministry to a

dental association rather than to a Baptist church or a synagogue or some other historically accepted religious institution.

As this Court stated in *U.S. v. Ballard*, 322 U.S. 78, 87 (1944), "[t]he First Amendment does not select any one group or any one type of religion for preferred treatment. It puts them all in that position. *Murdock v. Pennsylvania*, 319 U.S. 105, 63 S.Ct. 870, 891, 87 L.Ed. 1292, 146 A.L.R. 81."

Many of the major religions of the world also have strict dietary laws. Certainly, DCO's concern with natural herbs as based on the Hebrew Bible, which forms the foundation for the largest Western religions. Judaism and Christianity, of which DCO is a part, have a history of these beliefs as does Islam and many Eastern religions. Dietary religious practices are protected as part of the free exercise of religion. See, e.g., *Baranowski v. Hart*, 486 F.3d 112 (5th Cir. 2007.)

The D.C. Circuit's holding expands the jurisdiction of the FTC Act beyond what is allowed under the statute and the First Amendment's protection of the free exercise of religion. Accordingly, we respectfully submit that certiorari is proper.

II. A Religious Ministry Cannot Be Required to Rely Upon "Competent and Reliable Scientific Evidence Including Trials with Human Subjects" When Selling Herbal and Natural Dietary Supplements as Part of a Faith-Based Program to Its Parishioners

The standard imposed by the Commission, and upheld by the court of appeals, of requiring DCO to rely upon "'competent and reliable scientific evidence' including clinical trials with human subjects" exceeds what is authorized by statute. Pursuant to *Thompson Med. Co., Inc. v. FTC*, 791 F.2d 189, 193 (D.C. Cir.1986), that standard may properly be applied to a company marketing substances which purport to be drugs that are claimed to have a particular medical benefit. However, *Thompson Medical Co.*, is inapposite to the issue of what can be required of a religious ministry selling herbal products to its parishioners.

First, Thompson Medical Company was a pharmaceutical company rather than a church and religious ministry. *Thompson Med. Co, Inc, v. FTC*, 791 F.2d 189, 193 (D.C. Cir.1986). Second, the product at issue in *Thompson* was a drug rather than a dietary supplement. *Id.* Third, the advertisements in *Thompson* made a false factual claim about the composition of the drug. The Court stressed that Thompson Medical's advertising "strongly suggested" a false fact – "that Aspercreme and aspirin were somehow related." *Thompson*, 791 F.2d at 191.

In contrast, in this case, DCO is, first, a Biblically named church and religious ministry. Second, DCO

distributed dietary supplements through a website and radio show which clearly present the supplements as part of a faith-based program. Third, DCO made no false claims about the composition of the products. Under these circumstances, the FTC exceeded its authority by requiring that DCO support its products with the same pre-market testing standard as a pharmaceutical drug.

It is not only inappropriate, but short-sighted, to say that religious faith or herbal or natural dietary supplements cannot have a salutary effect on a person's well-being. The court of appeals went beyond the ordinary standard of a "reasonable basis" to impose the standard of "'competent and reliable scientific evidence' including clinical trials with human subjects." This standard blindly bans religious faith that the consumption of herbal supplements or other natural products can have a curative effect.

Within the last 150 years, for instance, scientists and medical doctors were prescribing mercury and arsenic while ignoring simple natural remedies such as hygiene, because medical science had not yet accepted the germ theory. The medical community did more harm in the name of science and rejected the natural approach to wellness through cleanliness.

We respectfully submit that a certain amount of freedom and alternative experimentation outside of clinical testing must be allowed and that the FTC does not have authority to treat a religious organization as if it were a drug company.

III. The FTC Act Cannot Trump the Protection Afforded a Religious Ministry by the First Amendment and RFRA

A religious ministry is afforded as a religious organization under the First Amendment to the United States Constitution and the Religious Freedom Restoration Act. The order upheld by the court of appeals mandating that DCO possess and rely upon competent and reliable scientific evidence violates RFRA by substantially burdening DCO's exercise of religion. See 42 U.S.C. § 2000bb-1(a). In addition, the letter required to be sent by the ministry to all its members also violates RFRA section 2000bb-1(a), as well as the free exercise of religion and freedom of speech guarantees of the First Amendment.

The Religious Freedom Restoration Act of 1993 (RFRA), 42 U.S.C. §§ 2000bb *et seq.*, provides that the federal government "shall not substantially burden a person's exercise of religion" unless "it demonstrates that application of the burden to the person – (1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest." 42 U.S.C. § 2000bb-1(b). RFRA applies to "all Federal law" and the implementation of that law, "whether statutory or otherwise," adopted both before and after the passage of RFRA. 42 U.S.C. § 2000bb-3(a). The purpose of RFRA was to restore, as a matter of statutory right, "the compelling interest test as set forth in *Sherbert v. Verner*, 374 U.S. 398 (1963) and *Wisconsin v. Yoder*, 406 U.S. 205 (1972) and to guarantee its application

in all cases where free exercise of religion is substantially burdened." 42 U.S.C. § 2000bb(b)(1). In so doing, Congress found that application of that test "as set forth in prior Federal court rulings" strikes a "sensible balance[ ] *5 between religious liberty and competing prior governmental interests." 42 U.S.C. § 2000bb(a)(5).

In particular, the order upheld by the court of appeals requires that DCO mail to all consumers, who purchased the products on or after January 1, 2005, to the date of service of the order, an "exact copy" of an FTC-composed letter and envelope (App. 11). The order requires DCO to include in the letter that: (1) "there is no 'scientific evidence' that any of the ingredients in [the products] are effective when used for prevention, treatment or cure of cancer"; (2) "it is important that you talk to your doctor or health care provider before using any herbal product . . . "; (3) "some herbal products may interfere or affect your cancer or other medical treatment, may keep your medicines from doing what they are supposed to do, or could be harmful when taken with other medicines . . . "; and (4) "it is also important that you talk to your doctor or health care provider before you decide to take any herbal product instead of taking cancer treatments that have been scientifically proven to be safe and effective in humans" (App. 16-17).

There are other legal remedies that might be pursued if there were fraud or if there were criminal acts. But what is at stake here is whether the FTC

can force a religious ministry to mail government authored statements. Indeed this federal agency seeks to force a ministry to say these government authored words verbatim in a letter as if they were uttered by the ministers. If this were within the FTC's jurisdiction, they could order Christian Scientists, or Muslims or Catholics to mail letters to their parishioners telling them that the government does not believe in their faith.

Under RFRA and the First Amendment to the United States Constitution, an FTC order cannot substantially burden any "exercise of religion," whether compelled by or central to a system of religious belief. 42 U.S.C. § 2000cc-5(7). According to the Supreme Court, exercise of religion is not limited to the positive expression of "belief and profession," but includes "abstention from physical acts." See *Employment Division, Dept. of Human Resources v. Smith*, 494 U.S. 872, 877 (1990). The order upheld by the court of appeals burdens DCO's exercise of religion by compelling James Feijo and his wife to send a letter to DCO's adherents that contains a message which contradicts their deeply held religious beliefs. The question of whether such an order violates the First Amendment and RFRA is a question worthy of certiorari.

CONCLUSION

For the reasons stated above, the petition for a writ of certiorari should be granted.

Dated: April 15, 2011

Respectfully submitted,

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United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 10-1064 **September Term, 2010**
FILED ON: DECEMBER 10, 2010

DANIEL CHAPTER ONE, A CORPORATE SOLE AND JAMES FEIJO, INDIVIDUALLY, AND AS OFFICER OF DANIEL CHAPTER ONE,

PETITIONERS

v.

FEDERAL TRADE COMMISSION,

RESPONDENT

On Petition for Review of an Order of the Federal Trade Commission

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Before: GINSBURG, HENDERSON and KAVANAUGH, *Circuit Judges*.

JUDGMENT

This petition was considered on the record from the Commission and on the briefs and the oral arguments of the parties. Although the issues presented occasion no need for a published opinion, they have been accorded full consideration by the Court. *See* Fed. R. App. P. 36; D.C. Cir. Rule 36(d). For the reasons stated in the accompanying memorandum, it is

ORDERED and **ADJUDGED** that the petition for review of the Order be denied.

The clerk is directed to withhold issuance of the mandate herein until seven days after resolution of any timely petition for rehearing or petition for rehearing en banc. *See* Fed. R. App. P. 41(b); D.C. Cir. Rule 41.

FOR THE COURT:
Mark J. Langer, Clerk

BY /s/
Michael C. McGrail
Deputy Clerk

MEMORANDUM

For the reasons set forth in this memorandum, we deny the petition filed by Daniel Chapter One and James Feijo (together, DCO) for review of the Federal Trade Commission's order.

First, the Commission properly exercised jurisdiction over DCO. Contrary to DCO's argument that its formal legal status as a religious "corporation sole" under Washington law prevents the FTC from regulating its advertisements, the jurisdictional inquiry properly focuses upon the substance of DCO' s activities. *See Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 766-68 (1999); *Cmty. Blood Bank v. FTC*, 405 F.2d 1011, 1018-19 (8th Cir. 1969). Because DCO operates, in substance, as a for-profit entity generating sales

revenue and providing "far more than *de minimis* or merely presumed economic benefits" to Feijo and his wife, the Commission had jurisdiction. *See Cal. Dental Ass'n*, 526 U.S. at 767-68.

Second, the Commission did not exceed its statutory authority by requiring DCO to have a reasonable basis for its claims. *See Thompson Med. Co. Inc. v. FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986) ("in general an advertisement is considered deceptive if the advertiser lacks a 'reasonable basis' to support the claims made in it"). Nor is there anything unreasonable about the specific type of basis required by the Commission, namely, "competent and reliable scientific evidence" including clinical trials with human subjects. Contrary to DCO's claim the FTC is "raising the bar" as to the type of support necessary for a reasonable basis, Pet'r Br. at 30, the Commission applied the analysis it has consistently used and which this court approved in *Thompson Medical*, 791 F.2d at 195. The Commission's published compliance guide, moreover, gave notice that a reasonable basis for a claim concerning a dietary supplement consists of scientific evidence, including clinical trials. *See* FTC, *Dietary Supplements: An Advertising Guide for Industry* (April 2001).[1] As noted in the guide, the Commission generally relies upon experts for evidence of the "accepted norms in the relevant field," *id.*, and

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[1] *Available at* http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry (visited Nov. 24, 2010).

the expert testimony before the Commission in the present case supports the type of substantiation it required of DCO.

We are not persuaded by DCO's complaint that the Commission has, on appeal, newly relied upon consumer impressions. The factors described in the guide and in the FTC's precedents, and applied by the Commission here, clearly focus upon what a message will "convey to consumers." *Id.*; *see also In re Pfizer, Inc.*, 81 F.T.C. 23 (1972). Because it is undisputed DCO did not support its claims with "competent and reliable scientific evidence" including clinical trials with human subjects, the Commission properly concluded DCO's advertisements were deceptive for want of a reasonable basis.

Finally, DCO's arguments based upon the Constitution and the Religious Freedom Restoration Act are wholly without merit. Deceptive commercial speech is entitled to no protection under the First Amendment and, even if it were, that would not preclude the Commission's order, which is carefully tailored to protect DCO's clientele from deception. *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 563-64 (1980); *Novartis Corp. v. FTC*, 223 F.3d 783, 788-89 (D.C. Cir. 2000). The Establishment Clause claim is based upon a faulty premise because "scientism" is not a religion. *Cf. Peloza v. Capistrano Unified Sch. Dist.*, 37 F.3d 517, 521-22 (9th Cir. 1994) ("neither the Supreme Court, nor this circuit, has ever held that evolutionism or secular humanism are 'religions' "). As for the RFRA claim, neither evidence

nor logic supports DCO's argument that religious tenets prevented sending its customers a letter with a message clearly attributed to the FTC.

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

In the Matter of	)	
	)	
DANIEL CHAPTER ONE, a corporation, and	)	
	)	
JAMES FEIJO, individually, and as an officer of Daniel Chapter One	)	**DOCKET NO. 9329**
	)	
	)	
	)	
	)	

MODIFIED FINAL ORDER

The Commission has heard this matter on the appeal of Respondents from the Initial Decision and on briefs and oral argument in support of and in opposition to the appeal. For the reasons stated in the accompanying Opinion of the Commission, the Commission has determined to enter the following order. Accordingly,

I.

IT IS HEREBY ORDERED that for purposes of this Order, the following definitions shall apply:

A. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other

evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

B. "Covered Product or Service" shall mean any dietary supplement, food, drug, or other health-related product, service, or program, including, but not limited to, BioShark, 7 Herb Formula, GDU, and BioMixx.

C. "Food" and "drug" shall mean "food" and "drug" as defined in Section 15 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 55.

D. "Advertisement" means any written or verbal statement, illustration, or depiction that is designed to effect a sale or to create interest in the purchasing of goods or services, whether it appears in a book, brochure, newspaper, magazine, pamphlet, leaflet, circular, mailer, book insert, letter, catalogue, poster, chart, billboard, public transit card, point of purchase display, packaging, package insert, label, film, slide, radio, television or cable television, video news release, audio program transmitted over a telephone system, infomercial, the Internet, e-mail, or in any other medium.

E. Unless otherwise specified, "Respondents" shall mean Daniel Chapter One and its successors and assigns, affiliates, or subsidiaries, and its officer, James Feijo, individually and as an officer of the

corporation; and each of the above's agents, representatives, and employees.

F. "Commerce" shall mean "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

G. "Endorsement" shall mean "endorsement" as defined in 16 C.F.R. § 255.0(b).

II.

IT IS HEREBY ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of BioShark, 7 Herb Formula, GDU, and BioMixx, or any substantially similar health-related program, service, or product, or any other Covered Product or Service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of product or program names or endorsements, that such health-related program, service, product, or Covered Product or Service prevents, treats, or cures or assists in the prevention, treatment, or cure of any type of tumor or cancer, including but not limited to representations that:

1. BioShark inhibits tumor growth;
2. BioShark is effective in the treatment of cancer;

3. 7 Herb Formula is effective in the treatment or cure of cancer;

4. 7 Herb Formula inhibits tumor formation;

5. GDU eliminates tumors;

6. GDU is effective in the treatment of cancer;

7. BioMixx is effective in the treatment of cancer; or

8. BioMixx heals the destructive effects of radiation or chemotherapy;

unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that Respondents, directly or through any person, corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product or Service, in or affecting commerce, shall not make any representation, in any manner, directly or by implication, including through the use of a product name, endorsement, depiction, or illustration, about the efficacy, performance, or health-related benefits of any Covered Product or Service unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and

reliable scientific evidence that substantiates the representation.

IV.

IT IS FURTHER ORDERED that:

A. Nothing in this order shall prohibit Respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. Nothing in this order shall prohibit Respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

V.

IT IS FURTHER ORDERED that:

A. Respondents shall, within seven (7) days after the final and effective date of this order, deliver to the Commission a list, in the form of a sworn affidavit, of all consumers who purchased BioShark, 7 Herb Formula, GDU, and/or BioMixx, on or after January 1, 2005 and until the date this order becomes final and effective. Such list shall include each

consumer's name and address, the product(s) purchased, and, if available, the consumer's telephone number and email address;

B. Within forty-five (45) days after the final and effective date of this order, Respondents shall send by first class mail, postage prepaid, an exact copy of the notice attached as Attachment A to all persons identified in Part V.A., above. The face of the envelope containing the notice shall be an exact copy of Attachment B. The mailing shall not include any other documents; and

C. Except as provided in this order, Respondents, and their officers, agents, servants, employees, attorneys, and representatives shall not sell, rent, lease, transfer, or otherwise disclose the name, address, telephone number, credit card number, bank account number, e-mail address, or other identifying information of any person who paid any money to any Respondent, at any time and until the date this order becomes final and effective, in connection with the purchase of BioShark, 7 Herb Formula, GDU, and/or BioMixx. *Provided, however*, that Respondents may disclose such identifying information to the FTC pursuant to Part V.A., above, or any law enforcement agency, or as required by any law, regulation, or court order.

VI.

IT IS FURTHER ORDERED that for a period of five (5) years after the last date of dissemination of

any representation covered by this order, Respondents shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All advertisements and promotional materials containing the representation;

B. All materials that were relied upon in disseminating the representation; and

C. All tests, reports, studies, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VII.

IT IS FURTHER ORDERED that Respondents shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the final and effective date of this order, and to future personnel within thirty

(30) days after the person assumes such position or responsibilities.

VIII.

IT IS FURTHER ORDERED that Respondent Feijo, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include the individual Respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

IX.

IT IS FURTHER ORDERED that Respondent DCO and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed

filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which Respondent DCO learns less than thirty (30) days prior to the date such action is to take place, Respondent DCO shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

X.

IT IS FURTHER ORDERED that Respondents shall, within sixty (60) days after the final and effective date of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

XI.

IT IS FURTHER ORDERED that this order will terminate on January 25, 2030, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that

the filing of such a complaint will not affect the duration of:

A. Any paragraph in this order that terminates in less than twenty (20) years;

B. This order's application to any Respondent that is not named as a defendant in such complaint; and

C. This order if such complaint is filed after the order has terminated pursuant to this paragraph.

Provided further, that if such complaint is dismissed or a federal court rules that the Respondents did not violate any provision of this order, and the dismissal is either not appealed or upheld on appeal, then the order will terminate according to this paragraph as though the complaint was never filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Donald S. Clark
Secretary

SEAL:
ISSUED: January 25, 2010

ATTACHMENT A
LETTER TO BE SENT BY FIRST CLASS MAIL
[To be printed on letterhead of Daniel Chapter One]

[Name and address of recipient] [Date]

Dear [Recipient]:

Our records show that you bought [**names of products**] from our website [**name of website**] or through a call center using our toll-free number. We are writing to tell you that the Federal Trade Commission ("FTC") has found our advertising claims for these products to be deceptive because they were not substantiated by competent and reliable scientific evidence, and the FTC has issued an Order prohibiting us from making these claims in the future.

The Order entered against us by the FTC requires that we send you the following information from the FTC about the scientific evidence on these products:

> Competent and reliable scientific evidence does not demonstrate that any of the ingredients in BioShark, 7 Herb Formula, GDU or BioMixx, are effective when used for prevention, treatment or cure of cancer.
>
> It is important that you talk to your doctor or health care provider before using any herbal product in order to ensure that all aspects of your medical treatment work together. Some herbal products may interfere or affect your cancer or other medical treatment, may keep your medicines from doing what they are

supposed to do, or could be harmful when taken with other medicines, or in high doses. It is also important that you talk to your doctor or health care provider before you decide to take any herbal product instead of taking cancer treatments that have been scientifically proven to be safe and effective in humans.

Sincerely,

ATTACHMENT B

Daniel Chapter One
1028 East Main Road
Portsmouth, Rhode Island, 02871

[name and address of purchaser]

GOVERNMENT ORDERED NOTICE

In the Matter of Daniel Chapter One and James Feijo
Docket No. 9329

OPINION OF THE COMMISSION

By ROSCH, Commissioner, For A Unanimous Commission:

Upon consideration of the record and the arguments of counsel, the Commission denies the Respondents' appeal and affirms the Initial Decision of the Administrative Law Judge both as a matter of fact and as a matter of law. The Commission finds the order entered below to be proper, but modifies the language in Attachment A of the Order, the prescribed notice that the Respondents are required to send to consumers who purchased the products at issue.

I. Background and Proceedings Below

The Commission issued tl Complaint in this matter on September 16, 2008 against Daniel Chapter One ("DCO") and James Feijo (collectively, "Respondents"). The Complaint alleged that Respondents engaged in deceptive acts or practices, in or affecting commerce, in violation of Sections 5(a) and 12 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. §§ 45(a) and 52. Compl. ¶ 17.

The Complaint alleged that these deceptive acts or practices occurred in connection with the Respondents' advertising, promotion, offering for sale and

distribution of four DCO products: BioShark, 7 Herb Formula, GDU and BioMixx (collectively, "the Challenged Products"), which purport to prevent, treat, or cure cancer or tumors and other serious medical illnesses. *Id.* ¶¶ 3-13.

More specifically, the Complaint alleged that advertisements for the Challenged Products represented, expressly or by implication, that:

- BioShark inhibits tumor growth and is effective in the treatment of cancer;
- 7 Herb Formula inhibits tumor growth and is effective in the treatment or cure of cancer;
- GDU eliminates tumors and is effective in the treatment of cancer; and
- BioMixx heals the destructive effects of radiation and chemotherapy and is effective in the treatment of cancer.

Id. ¶ 14. The Complaint alleged that those representations were deceptive in that Respondents represented, directly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations when in fact Respondents lacked a reasonable basis to substantiate them. *Id.* ¶¶ 15-17.

Respondents filed their Answer on October 11, 2008. The Answer admitted that Respondents made the representations alleged in the Complaint about the efficacy of the Challenged Products. Answer ¶ 14. The Answer also admitted that Respondents operated a website that provided information respecting the

Challenged Products in a religious and educational context, but otherwise denied the allegations that they engaged in deceptive acts or practices in connection with the advertising or sale of the Challenged Products. *Id.* ¶¶ 5, 7, 9, 11, 13-15. The Answer affirmatively averred that Respondents possessed and relied upon a reasonable basis that substantiated the representations made about the Challenged Products at the time the representations were made. *Id.* ¶ 16.

Respondents filed two motions to amend their Answer. Chief Administrative Law Judge D. Michael Chappell ("ALJ"), who presided over all pretrial proceedings and the trial, denied those motions on the grounds, *inter alia,* that the proposed amendments, coming after the close of discovery and approximately two months before trial, would have been unduly prejudicial to Complaint Counsel. Respondents also filed two motions to dismiss, and cross-motions for summary judgment were filed by Respondents and Complaint Counsel. Those motions were denied.

An evidentiary hearing on jurisdiction was held on April 21, 2009. Thereafter, the ALJ issued a ruling that Complaint Counsel had demonstrated, by a preponderance of evidence, that jurisdiction existed in the case. Respondents' motion for an interlocutory appeal from that ruling was denied.

The final pre-trial conference was held on April 22, 2009, with trial commencing immediately thereafter. Following trial, Respondents and Complaint

Counsel filed concurrent post-trial briefs, proposed findings of fact and conclusions of law, and replies to each other's post trial briefs and proposed findings. Closing argument was held on July 9, 2009. The ALJ issued his Initial Decision and Proposed Order on August 5, 2009.

As set forth in the Initial Decision, the ALJ found that the record showed that DCO, described by the Respondents as a house ministry, was led by Respondent James Feijo, with his wife Patricia Feijo, and that DCO engaged in business for profit for itself or for its member, James Feijo. The ALJ found that, although DCO's activities included spiritual counseling to individuals, they also included advertising and selling the dietary supplements BioShark, 7 Herb Formula, GDU and BioMixx to the public.

The ALJ also found that Respondents disseminated advertisements for the purpose of inducing, and which did induce, the purchase of a food or drug, in or having an effect on commerce within the meaning of Sections 5(a) and 12 of the FTC Act, and that those advertisements claimed that the Challenged Products, individually or collectively, prevent, treat, or cure cancer, inhibit tumors, or ameliorate the adverse effects of radiation and chemotherapy. The ALJ also found that Respondents did not have a reasonable basis to substantiate these claims and that the claims made were material to consumers.

The ALJ held that Complaint Counsel had carried its burden of proving that Respondents are liable

under Sections 5(a) and 12 of the FTC Act. The ALJ considered the defenses raised by the Respondents and concluded that they were not meritorious. The ALJ imposed a cease and desist order that, *inter alia*, enjoins Respondents from making any representation, expressly or by implication, that any dietary supplement, food, drug, or other health-related product, service, or program, including but not limited to the Challenged Products, prevents, treats, cures or assists in the prevention, treatment, or cure of any type of tumor or cancer, unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

The order also enjoins the Respondents from making any representation about the efficacy, performance, or health-related benefits of any dietary supplement, food, drug, or other health-related product, service, or program, including but not limited to the Challenged Products, unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

The order also requires the Respondents to send a prescribed notice to all consumers who purchased the Challenged Products that informs those consumers that the FTC has found that the advertising claims at issue were false and unsubstantiated, that the FTC has issued an order prohibiting those claims

from being made in the future, and that informs those consumers about the scientific evidence on the Challenged Products.

Respondents filed a timely appeal and Complaint Counsel did not cross-appeal. The decision of the ALJ is subject to *de novo* review by the Commission. *See* 16 C.F.R. § 3.54. Accordingly, the Commission on appeal may consider the entire record and determine whether there is a sufficient evidentiary basis for the ALJ's findings of fact.

The Commission has reviewed the ALJ's findings of fact, as well as the record underlying them. The Commission has also reviewed the advertisements at issue to determine the overall net impressions conveyed by them. The Commission sees no reason to disturb the ALJ's findings of fact and adopts them as the Commission's own insofar as they are consistent with those set forth in this Opinion. Otherwise, the findings of fact in this Opinion are those of the Commission.

II. Respondents' Claims on Appeal

Respondents make three fundamental claims in their appeal: (1) Respondents claim that the FTC did not have jurisdiction over them (RAB at 11, 29-40);[1]

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[1] References to the record are abbreviated as follows:

IDF Initial Decision Finding
ID Initial Decision
RAB Respondents' Appellate Brief

(Continued on following page)

(2) Respondents claim that the ALJ misinterpreted various statutes, including, among others, Section 5 of the FTC Act, as well as the Due Process Clause and the First Amendment of the United States Constitution, by banning truthful statements about dietary supplements, improperly shifting the burden of proof to Respondents, applying an incorrect standard of proof, and permitting "evidence by presumption" (RAB at 11-29, 40-55); and (3) Respondents argue that the ALJ's remedy not only prohibits truthful speech, but also illegally compels Respondents to engage in government-mandated speech. RAB at 12, 55-65.

The Commission considers the Respondents' arguments in Part III in the following order: Section A considers the Respondents' jurisdictional argument; Sections B through E consider Respondents' statutory and constitutional arguments; and Section F considers the Respondents' argument concerning the remedy.

III. Analysis

A. The FTC Has Jurisdiction.

Findings of Fact.

Prior to 2002, DCO was a for-profit corporation organized in 1990 under the laws of Rhode Island.

CAB Complaint Counsel's Answering Brief
RRB Respondents' Reply Brief
Tr. Transcript of Trial Testimony
CX Complaint Counsel's Exhibit
RX Respondents' Exhibit

IDF 22. Its Articles of Incorporation stated that its purposes were "to engage in the sale, retail, wholesale and distribution of health products, including but not limited to health foods and supplements, namely those with special nutritive qualities and values." IDF 23. Subsequent annual reports, which were signed by Respondent James Feijo, described the character of the business in substantially the same way. IDF 24, 25. James Feijo sold BioShark, 7 Herb Formula, GDU and BioMixx while DCO was registered as a for-profit corporation. IDF 27.

DCO is currently a "corporation sole" organized in 2002 under the laws of the State of Washington. IDF 1; RAB at 30, 32. DCO's Articles of Incorporation do not specifically declare that DCO was organized exclusively for charitable or other clearly nonprofit purposes. IDF 30. The Articles do not provide for distribution of its assets upon dissolution solely to other nonprofit entities or prohibit distribution of its earnings to the benefit of any individual or for-profit corporation. *Id.* Nor do its advertising or promotional materials specifically refer to DCO as a nonprofit entity. IDF 32.

Respondent James Feijo is the sole "overseer" and trustee of DCO's assets and all of its funds, and he is DCO's sole "member." IDF 5, 6; RRE at 8. As such, he is responsible for all of its activities and for directing all of its funds. IDF 5, 6. James Feijo and his wife, Patricia, are the only officers of DCO. IDF 7.

DCO has a number of bank accounts, including accounts that are described as "Business Partner" accounts. IDF 42. DCO's revenue is deposited into the Business Partners Checking accounts, and from there the revenue is distributed at James Feijo's discretion to other DCO bank accounts. IDF 42. Patricia Feijo is a signatory to DCO's bank accounts and writes checks from the DCO accounts. IDF 48. The Business Partners Money Market Fund showed a balance during the period from December 19, 2006 to February 20, 2008 in excess of $1 million, but on February 21, 2008, a debit of over $800,000 was posted. IDF 45.

DCO or its affiliate own the Rhode Island and Florida homes in which James and Patricia Feijo live, as well as two Cadillacs that James Feijo uses. ID at 75; IDF 55-57. DCO paid for all of the Feijos' living expenses, including pool and gardening expenses, tennis and golf club expenses, as well as the Feijos' expenditures on retail items and at restaurants. IDF 58, 61-70.

DCO currently sells 150 to 200 products, including BioShark, 7 Herb Formula, GDU and BioMixx. IDF 8. James Feijo has been solely responsible for the development, creation, production, and pricing of the Challenged Products. IDF 37. James and Patricia Feijo have been solely responsible for creating, drafting and approving directions for the usage, and developing recommended dosages, for the Challenged Products. IDF 38, 39.

Sales of the 150 to 200 products sold by DCO, all of which are dietary supplements, have generated approximately $2 million in annual gross sales. IDF 9, 10. DCO's sales of BioShark, 7 Herb Formula, GDU and BioMixx constituted 20 to 30 percent of DCO's sales during the period from 2006 through 2008. IDF 80. The acquisition costs for those products is about 30 percent of the sale price. IDF 83.

Over a thousand people have purchased the Challenged Products, including people who do not belong to any DCO religious community and people who do not believe in God. IDF 81, 82. Respondents sell the four Challenged Products through publications, a call center, a radio program, over the Internet, and through stores and other resellers. IDF 84, 158. Any consumer could be directed to the DCO website by entering the term "cancer" in a Google internet search. IDF 162.

DCO's publications are fourfold. The first is entitled "Bioguide: The BioMolecular Nutrition Guide to Natural Health" ("BioGuide"), which was prepared by James Feijo, describes "two aspects of Bio-Molecular Nutrition, the spiritual and the physical" and promotes all four Challenged Products. IDF 203-211, 228, 229, 249, 270-274, 287-290. The second publication is the BioMolecular Nutrition Product Catalog ("Product Catalog"), which describes all of DCO's products including the four Challenged Products, but does not mention the existence of a DCO ministry. IDF 91, 233, 234, 256, 257, 279, 280. The third publication is a newsletter entitled "How to

Fight Cancer is *Your* Choice!!!" ("Newsletter"), which promotes all four of the Challenged Products. IDF 94-96, 194-201, 231, 251, 253, 254, 276, 277, 292, 293. The fourth publication is entitled "The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide" ("Most Simple Guide"). It also promotes the four Challenged Products. IDF 192. The Most Simple Guide, the BioGuide, and the Newsletter are all available to anyone by download from DCO's website. IDF 163, 169, 172.

Each of these publications promotes DCO's call center and the toll-free number to access it, as well as DCO's principal website address. IDF 90, 91, 94, 167, 174. The Newsletter promotes the BioGuide and the Most Simple Guide. IDF 168, 175. All except the Product Catalog promote the radio program. IDF 177.

As previously mentioned, DCO has a toll-free number and a call center for consumers to buy their products. IDF 99. They were created, managed and maintained by James Feijo, who has supervised the call center and taken consumer orders. IDF 100, 101. DCO also has several websites at which it takes consumers' orders, the principal one of which invites consumers to shop at DCO's "On-Line Store" and to "Buy Now." IDF 103-107. These websites promote all four of the Challenged Products. IDF 179-190, 220-226, 237-244, 246, 247, 262-268, 283-286.

DCO also has a radio program, which is co-hosted by James and Patricia Feijo for two hours a day. IDF 108, 109. On that program, the Feijos have promoted

the Challenged Products. IDF 213-217, 260, 261. They have also counseled individuals who have identified themselves as cancer patients, and they (and the website) have provided listeners with the toll-free number they can use to buy DCO's products. IDF 102, 110, 111.

A number of retail stores and chiropractic centers in various states sell DCO products. IDF 116-119. Respondents have prepared a brochure entitled "The Truth Will Set You Free" for retailers of DCO products. Among the benefits listed in that brochure are financial rewards, and the brochure makes the representation that DCO is "the ONLY nutrition company where the owners personally tell thousands of people to visit your office or store." IDF 122. Respondents also promote an "affiliate program" on their principal web page where they offer website owners "a means of profiting from their websites" by "generat[ing] sales for commercial websites" in order to "earn a commission." IDF 123.

To promote its products, DCO offers consumers coupons for their next online order, and discounts when products are purchased in volume. IDF 113-115. Moreover, in addition to the revenue derived from sale of its products, DCO charges shipping and handling fees totaling $20.95. IDF 112.

Legal Analysis.

On appeal, Respondents argue that the ALJ was mistaken and incorrect in concluding that the FTC

had jurisdiction over DCO. In support of this contention, Respondents rely on several alleged Due Process errors and misapplications of law by the ALJ. RAB at 31. Specifically, Respondents argue that the ALJ misapplied the applicable law regarding jurisdiction; disregarded DCO's status as a corporation sole, a legitimate entity outside the FTC's jurisdiction; failed to require Complaint Counsel to prove that DCO is a corporation "organized to carry on business for its own profit or that of its members;" and failed to prove that DCO or its members "derived a profit from DCO's activities." RAB 31-40. These arguments are each considered below.

As Respondents acknowledge in their appellate briefs, *California Dental Ass'n v. FTC,* 526 U.S. 756 (1999) and *Community Blood Bank v. FTC,* 405 F.2d 1011 (8th Cir. 1969), are controlling authorities respecting their challenge to the FTC's jurisdiction. RAB at 31, 34; RRB at 17. Both cases, following the language of § 4 of the FTC Act, hold that the Commission's jurisdiction extends to a corporation organized to carry on business for its own profit or that of its members. *See California Dental,* 526 U.S. at 766-67 ("The FTC Act is at pains to include not only an entity 'organized to carry on business for its own profit,' . . . but also one that carries on business for the profit 'of its members' "); *Community Blood Bank,* 405 F.2d at 1022 (holding the Commission has jurisdiction over nonprofit corporations without shares of capital, which engage in business for their own profit or that of their members); *see also* 15 U.S.C. § 44.

Respondents try to distinguish these cases from the instant case by parsing the definition of "profit" and by arguing that, contrary to the teaching of *California Dental,* DCO did not make a profit and has no for-profit subsidiaries. RAB at 32. Specifically, Respondents quote *California Dental* for the proposition that "according to a generally accepted definition 'profit' means gain from business or investment over and above expenditures, or gain made on business or investment where both receipts or payments are taken into account." RAB at 32 (*quoting California Dental,* 526 U.S. at 768 n.6 (*citing Community Blood Bank,* 405 F.2d at 1017)). However, the ALJ cited to the same *California Dental* language in evaluating the evidence and reaching his conclusion that by engaging in commercial activities, DCO operates a commercial enterprise and thereby is not a business organized or engaged in only charitable purposes. ID at 70-71. In addition, Respondents failed to include the conclusion of the quoted sentence where the Court noted that "the 'term's meaning must be derived from the context in which it is used.'" *California Dental,* 526 U.S. at 768 n.6 (*citing Community Blood Bank,* 405 F.2d at 1016).

Respondents contend that they are a religious ministry organized and operated for charitable purposes. RAB at 2, 31. Respondents argue that by acknowledging that DCO was a religious ministry, but still concluding that the FTC had jurisdiction over DCO, the ALJ's conclusions are "unprecedented, legally incorrect and unsupported by the facts." RAB

at 4, 2930. But *Community Blood Bank* specifically holds that such a finding does not foreclose the FTC from exercising jurisdiction over a respondent. 405 F.2d at 1017-18; *see also id.* at 1018 ("Congress took pains in drafting § 4 to authorize the Commission to regulate so-called nonprofit corporations, associations and all other entities if they are in fact profit-making enterprises."). Nonprofit status insulates an entity from FTC jurisdiction when the entity is engaged in business for "only charitable purposes." *Id.* at 1022. Whatever else may be said about DCO's religious status and activities, the findings of fact, supported by extensive evidence, establish that DCO conducted business for the purpose and with the effect of selling its products, including the four Challenged Products. IDF 80-84, 91, 94, 96, 98-101, 110-113, 116-119, 123, 158, 174-190, 192, 194-201, 203-211, 213-217, 220-229, 231, 233, 234, 237-244, 246, 247, 249, 253, 254, 256, 257, 260-268, 270-274, 276, 277, 279, 280, 283-290, 292, 293. Thus, the ALJ did nothing to impeach his conclusion that the FTC had jurisdiction over Respondents.

The Respondents also argue that the ALJ failed to require proof that DCO was organized and operated to carry on business for its own profit or that of its members. RAB at 30, 34-35. In support of this contention, Respondents insist that DCO was not a for-profit corporation because it did not "make a profit" and that "the evidence showed the DCO operates at a breakeven point or less." RAB at 30, 35. Whether or not that is true, it is beside the point. As the ALJ

pointed out, it is not necessary to show that the entity was actually successful in running its business or turning a profit. ID at 71 (*citing California Dental*, 526 U.S. at 768 n.6 ("the FTC Act does not require for Commission jurisdiction that members of an entity turn a profit on their membership, but only that the entity be organized to carry on business for members' profit"); *In re Ohio Christian College*, 80 F.T.C. 815, 849-50 (1972) (stating that the fact that respondents "were apparently not very successful in their enterprise" was of "little consequence")). As discussed above, Respondents' activities, as described in the findings of fact, and supported by extensive evidence, establish that DCO conducted business for the purpose and with the effect of selling its products.

Moreover, in *In re College Football Ass'n*, 117 F.T.C. 971, 994 (1994), the Commission stated that *Community Blood Bank* thus established a two-part test looking to "the source of the entity's income, *i.e.*, to whether the corporation is 'organized for and actually engaged in business for only charitable purposes,' and to the destination of the income, *i.e.*, to whether either the corporation or its members derive a profit." Respondents contend that the FTC must also show the "destination" of DCO's income, and argue that the ALJ improperly shifted the burden of proof from the FTC to the Respondents to show that the income did not profit either DCO or Mr. Feijo. RAB at 35-36. However, the ALJ's findings of fact, supported by ample evidence, show that the "destination" of the profits of DCO's for-profit activities was

James Feijo. ID at 74-76. As DCO's sole "member," "overseer," and "trustee," James Feijo was responsible for all of DCO's activities, including the distribution of its funds; he distributed those funds to himself and his wife for their benefit. The record also shows that DCO or its affiliate owned the Feijos' Rhode Island and Florida homes and two Cadillacs, and was the source of all of their living expenses, including their tennis, golf and restaurant expenses. IDF 5, 6, 42, 48, 55-58, 61-70. Thus, it cannot be said that the ALJ's conclusion that the FTC had jurisdiction over DCO was "unprecedented." RAB at 11; RRB at 12, 14, 21-22. To the contrary, it was fully supported by *California Dental* and *Community Blood Bank*.

Finally, it cannot be said that the ALJ was "mistaken" in exercising jurisdiction over DCO and Mr. Feijo despite the existence of various statutes and regulations that allow churches to carry on "business activities" for purposes of exemption from federal income taxation or provide "religious workers' special exemptions." RAB at 38-40. Respondents argue that DCO's status as a church and Mr. Feijo's status as a minister entitle Respondents to special tax treatment. RAB at 39. Similarly, Respondents contend that DCO was organized as a "corporation sole" in 2002 under the laws of the State of Washington, and, as such, has been a nonprofit corporation since 2002. RAB at 29-31. As recognized by the ALJ, however, "courts and the Commission look to the substance, rather than the form, of incorporation in determining jurisdiction under the FTC Act." ID at 71 (citations

omitted). The Commission agrees with the ALJ's determination, supported by ample evidence in the record, that "DCO bears none of the substantive indicia of a corporation that is truly organized only for charitable purposes." *Id.*

B. Respondents Made the Claims Alleged in the Complaint.

Findings of Fact.

The text of the advertisements at issue here repeatedly links all four products collectively to the prevention, treatment or cure of cancer. IDF 179, 180, 183, 186, 190, 192, 195, 197, 200, 203, 204, 208, 213. Furthermore, the advertisements repeatedly link each product individually to the cure or treatment of cancer, the shrinkage of tumors, or, in the case of BioMixx, to the amelioration of the side effects of radiation and chemotherapy. IDF 182, 198, 199, 204, 206, 221, 222, 223, 225, 226, 228, 231, 233 (respecting BioShark); IDF 237-244, 246, 247, 249, 251-254, 256, 257, 260 (respecting 7 Herb Formula); IDF 262, 264-268, 270-274, 276, 277, 279, 280 (respecting GDU); IDF 283-285, 287-290, 292, 293 (respecting BioMixx). Indeed, in some of these advertisements the linkage between these products and the treatment or cure of cancer is to a specific type of cancer such as breast cancer (IDF 182, 187, 265, 267, 268, 273); brain cancer (IDF 184, 200, 249, 289); prostate cancer (IDF 187, 206 253, 265, 271, 274, 290); skin cancer (IDF 208, 214); colon cancer (IDF 217, 260); leukemia (IDF

276, 284); bladder cancer (IDF 200); renal cancer (IDF 207); and esophageal cancer (IDF 252). Generally, these links were explicit, but even when they were implicit, the linkage was clear.

The linkage in these advertisements was frequently emphasized by testimonials, generally by consumers. IDF 180, 181, 183, 184, 186, 197-200, 203-210, 231, 242-244, 247, 249, 253, 265, 267, 268, 273, 276, 284, 290, 292. Again, the linkage in the testimonials between the products and the treatment or cure of cancer, the shrinkage of tumors or, in the case of BioMixx, to the healing effects on radiation or chemotherapy was generally explicit, but even where it was implicit, the linkage was clear. That linkage was also frequently stressed either by the use of bold-faced type, the use of italics or the use of capital letters. IDF 180, 182, 186, 187, 190, 192, 204-209, 221, 226, 228, 231, 237, 238, 240-243, 249, 252-254, 266, 271, 274, 276, 283, 285, 289. Additionally, the products or consumers purporting to use them were depicted in the advertisements. IDF 180, 184, 190, 204, 206-208, 210, 221, 237, 238, 240, 241, 251 (logo), 254 (logo), 256, 262, 263, 266, 271, 276, 279, 283-285, 290.

These advertisements did not exist in isolation from each other. As previously described, DCO's publications prominently displayed the existence of DCO's call center and the toll-free number by which the call center could be accessed, as well as DCO's principal website address. IDF 90, 91, 98, 167-169, 174. Also, the Newsletter promoted the BioGuide and The Most Simple Guide, and the call center promoted

the DCO email address. IDF 168, 175-177. Thus, the overall net impressions left by these advertisements were mutually reinforcing.

Those overall net impressions were that: (1) BioShark inhibits tumor growth and is effective in the prevention, treatment, or cure of cancer (IDF 224, 227, 230, 232, 235); (2) 7 Herb Formula inhibits tumor formation and is effective in the prevention, treatment, or cure of cancer (IDF 245, 248, 250, 255, 258); (3) GDU eliminates tumors and is an effective treatment for cancer (IDF 269, 275, 278, 281); and (4) BioMixx heals the adverse effects of radiation and chemotherapy and is effective in the prevention, treatment, or cure of cancer. IDF 286, 291, 294.

Respondents' advertisements and materials sometimes included "disclaimers" of these overall net impressions. DCO's websites asserted, *inter alia*, that "[t]he information provided in this site is not intended to diagnose a disease;" that the information "is designed to support, not replace, the relationship that exists between a patient site visitor and his/her health provider;" and that "this product is not intended to diagnose, treat, cure, or prevent disease." IDF 296, 297, 300, 301. The BioGuide and Newsletter stated, *inter alia*, that they were "not intended to diagnose or treat disease." IDF 298, 299. The Most Simple Guide contains no disclaimer language. IDF 302.

For the most part, these disclaimers were made in "mouse print" or type size significantly smaller

than the type of the text contributing to those overall net impressions. IDF 296, 298-300, 303. They were often buried in copyright disclosures, and placed well after the conclusion of the advertising claims. IDF 296-300. Moreover, they disclaimed only Respondents' "intentions," not the representations themselves. They did not dispel the overall net impressions left by the advertisements and by the other contributing factors that the Challenged Products prevent, treat, or cure cancer. IDF 306.

Legal Analysis.

Respondents do not take issue with the ALJ's conclusion that the "overall net impression" of the advertising promoting the four Challenged Products determines what impression is conveyed by an advertisement. RAB at 4, 5, 11; RRB at 38. That acknowledgment is not gratuitous. The courts have long held that to be the test applied in determining what impressions are conveyed to consumers. *See, e.g., American Home Prods. Corp. v. FTC*, 695 F.2d 681, 687 (3rd Cir. 1982); *FTC v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963); *FTC v. Bronson Partners LLC*, 564 F. Supp. 2d 119, 125 (D. Conn. 2008); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 920-21, 929, 932 (N.D. Ill. 2006), *aff'd*, 512 F.3d 858 (7th Cir. 2008). Moreover, Respondents admitted that they made the representations that the ALJ found were conveyed by the advertisements at issue (Answer ¶ 14), although now Respondents shrug off the admissions as "ministerial

error" and stress that the ALJ did not consider them. RBB [sic] at 35.

However, Respondents repeatedly assert that in assessing those "overall net impressions," the ALJ was obliged by the Due Process Clause and the First Amendment of the Constitution to consider "extrinsic" evidence. RAB at 2, 4, 13, 48-49; RRB at 12-13, 30-31. More specifically, Respondents claim that "Complaint Counsel should have been required to produce evidence that consumers were actually misled by Respondents' promotional efforts and representations," including testimony from the misled consumers themselves. RAB at 14, 23-24; RRB at 33, 34, 37-38, 57. Indeed, Respondents contend that the ALJ's failure to require Complaint Counsel to do so amounted to resorting to "presumptions" instead of evidence or at least "shifting the burden of proof" to Respondents in violation of the Due Process Clause and the First Amendment. RAB at 3, 11, 14, 24.

That is not the law. Federal courts have long held that the Commission has the common sense and expertise to determine "what claims, including implied ones, are conveyed in a challenged advertisement, so long as those claims are reasonably clear." *Kraft, Inc. v. FTC*, 970 F.2d 311, 319 (7th Cir. 1992); *accord FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 391-92 (1965); *Thompson Med. Co. v. FTC*, 791 F.2d 189, 197 (D.C. Cir. 1986); *Bronson Partners*, 564 F. Supp. 2d at 126; *FTC v. Nat'l Urological Group, Inc.*, No. 1:04-CV-3294-CAP, 2008 U.S. Dist. LEXIS 44145, at *41-43 (N.D. Ga. June 4, 2008) (extrinsic

evidence "is only necessary when the asserted claims fall on the 'barely discernable' side of the continuum"); *QT, Inc.*, 448 F. Supp. 2d at 958.

Moreover, in *Kraft*, the Seventh Circuit rejected Respondents' First Amendment argument. Like Respondents, Kraft contended that *Peel v. Attorney Registration & Disciplinary Commission*, 496 U.S. 91 (1990), held that the First Amendment required "extrinsic" evidence and prevented the Commission from determining the overall net impression conveyed by advertisements challenged as deceptive under the FTC Act. The Court of Appeals held that the restriction challenged in *Peel* is "a completely different animal than the one challenged here." *Kraft*, 970 F.2d at 317. It explained that in *Peel*, the issue was whether a "regulation applicable to all lawyers, completely prohibiting an entire category of potentially misleading speech, passed constitutional muster" in contrast to "whether an individualized FTC cease and desist order, prohibiting a particular set of deceptive ads, passes constitutional muster." *Id.*

In this case, the ALJ and the Commission itself have determined the "overall net impressions" of the representations made about the Challenged Products, based not only on the text of the advertisements itself, but also on the interaction of other factors that operate to create that impression, such as testimonials, bold type, visual images and mutually reinforcing language. ID at 82-83. Those are factors that the Commission and the courts have recognized are probative in determining what messages advertising

is conveying. *In re Kraft,* 114 F.T.C. 40, 121 (1991), *aff'd,* 970 F.2d 311 (7th Cir. 1992); *see also Bronson Partners,* 564 F. Supp. 2d at 125; *In re Telebrands Corp.*, 140 F.T.C. 278, 290 (2005), *aff'd,* 457 F.3d 354 (4th Cir. 2006). The Commission therefore does not agree with Respondents that "evidence" has been supplanted by "presumptions" or that the ALJ shifted the "burden of proof" to Respondents so as to violate Due Process or the First Amendment of the Constitution in the determination of those overall net impressions.

As discussed below, the alleged "disclaimers" do not dispel these overall net impressions.

C. Respondents' Representations Were Deceptive Unless Properly Substantiated.

After reaching his findings on the overall net impressions of the Respondents's advertising respecting the efficacy of the four Challenged Products, the ALJ next examined whether those representations were deceptive under Commission and federal case law. He concluded that under that case law, the representations would be deceptive under Sections 5 and 12 of the FTC Act if they were either shown to be false or shown to lack a reasonable basis substantiating the claims made in the advertisement. ID at 99 (*citing FTC v. Pantron I,* 33 F.3d 1088, 1096 (9th Cir. 1994); *In re Thompson Med. Co.,* 104 F.T.C. 648, 818-19 (1984), *aff'd,* 791 F.2d 189 (D.C. Cir. 1986)).

The ALJ focused on whether the advertisements at issue were deceptive or misleading under the "reasonable basis" theory because the Complaint only made "reasonable basis" allegations. *Id.* Again, citing Commission and federal case law, the ALJ stated that the "reasonable basis theory holds that claims about a product's attributes, performance, or efficacy ('objective' product claims) carry with them the express or implied representation that the advertiser had a reasonable basis substantiating the claims at the time the claims were made." *Id.* (*citing In re Thompson Med. Co.*, 104 F.T.C. at 813; *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d 285, 298 (D. Mass. 2008); *In re Kroger Co.*, No. C-9102, 1978 FTC LEXIS 332, at *15 (May 17, 1978)).

Respondents do not (and cannot) dispute that this is a correct reading of the case law. However, Respondents contend that in applying these principles, the ALJ again engaged in "presumptions" and shifted the "burden of proof" in a way that violated the Due Process Clause and the First Amendment of the Constitution. RRB at 34, 51.

First, Respondents contend that the representations made about the efficacy of the four Challenged Products cannot be challenged as deceptive, consistent with the First Amendment. Specifically, Respondents liken those representations to mere "ideas, opinions, beliefs and theories" involved in *In re Rodale Press, Inc.*, 71 F.T.C. 1184 (1967), to a ban on the words "natural," "organic" and "health food" which an FTC Presiding Officer condemned in

connection with the Commission's Proposed Trade Regulation Rule on Food Advertising ("Food Rulemaking") (Report of the Presiding Officer, Proposed Trade Regulation Rule: Food Advertising, Pub. Rec. No. 215-40, at 239, Feb. 21, 1978), and with the representations about "matters of opinion" involved in *United States v. Johnson,* 221 U.S. 488 (1911). RAB at 5-11.

Respondents' representations are not matters of opinion, but, as the ALJ put it, "objective product claims . . . stated in positive terms and . . . not qualified to be statements of opinion." ID at 99. Or, to put the matter more baldly, Respondents' representations were representations of fact, not simply representations about ideas, opinions, beliefs or theories; Respondents made assertions not just about what they believed those products might do, but represented that the four Challenged Products would in fact treat or cure cancer, prevent or shrink tumors, and ameliorate the side effects of radiation and chemotherapy. *See, e.g.,* IDF 179, 180, 183,186, 190, 192, 195, 197, 200, 203, 204, 208, 213 (Challenged Products collectively); IDF 221-223, 225, 226, 228, 231, 233 (BioShark); IDF 182, 198, 199, 204, 206, 237-244, 246, 247, 249, 251-254, 256, 257, 260 (7 Herb Formula); IDF 262, 264-268, 270-274, 276, 277, 279, 280 (GDU); IDF 283-285, 287-290, 292, 293 (BioMixx). Therefore, as a matter of law, there was an implied claim that there was a reasonable basis substantiating those representations. *In re Thompson Med. Co.,* 104 F.T.C. at 813 n.37 (noting that "objective product

claims carry with them an express or implied statement that the advertiser has some amount of support for the claim").

Beyond that, *Rodale Press,* the Food Rulemaking, and the *Johnson* case were not decided on constitutional grounds. As Respondents acknowledge, the Commission simply voted to dismiss *Rodale Press.* RAB at 6. Similarly, the Commission abandoned its Proposed Trade Regulation Rule on Food Advertising on the ground that case-by-case scrutiny would be more appropriate. *See* Food Advertising, 45 Fed. Reg. 23705 (Apr. 8, 1980); Termination of Proposed Trade Regulation, 48 Fed. Reg. 23270 (May 24, 1983). In neither instance was the Commission's action compelled by the First Amendment. *See, e.g.,* 45 Fed. Reg. at 23706 (stating that "it is not clear that the claims under scrutiny are readily susceptible to the across-the-board remedies that have been proposed or that this approach represents the ideal solution for remedying deception or unfairness"); *Rodale Press, Inc. v. FTC,* 407 F.2d 1252 (D.C. Cir. 1968) (vacating Commission's order and remanding for further hearing and argument on new theory of violation); *In re Rodale Press, Inc.,* 74 F.T.C. 1429, 1430 (1968) (dismissing complaint because, "[f]urther continuation of these proceedings at this time appearing not to be in the public interest and the possibility appearing remote that the practices challenged in the complaint would be resumed in the future"). Respondents likewise acknowledge that "[t]he *Johnson* case did not reach the constitutional question because the

majority disposed of it as a legislative interpretation case." RAB at 11. Indeed, as the ALJ pointed out, Congress effectively overruled *Johnson* by amending the Food and Drug Act to expressly include claims regarding curative effectiveness. ID at 111 (*citing* Act of June 30, 1906, as amended, 37 Stat. 416 (1912)).

Additionally, Respondents' representations are not protected by the First Amendment. It is well established under applicable Supreme Court precedent that commercial speech is accorded less protection than other constitutionally protected forms of speech. ID at 112 (*citing Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 562-63 (1980); *Va. Pharm. Bd. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 771-72 n.24 (1976)). In determining whether speech is commercial, *Zauderer v. Office of Disciplinary Council,* 471 U.S. 626, 637-38 (1985), is instructive. *Zauderer* holds that the determination of whether speech is commercial speech "rests heavily on 'the common sense distinction between speech proposing a commercial transaction . . . and other varieties of speech.'" ID at 113 (citations omitted). Thus, as the ALJ pointed out in the Initial Decision, speech that "propose[s] a commercial transaction" necessarily constitutes commercial speech. *Id.* (*citing Bd. of Trs. of State Univ. of N.Y. v. Fox,* 492 US. 469, 473-74 (1989)).

As previously discussed in connection with Respondents' jurisdictional challenge, the primary purpose and effect of Respondents' representations concerning the four Challenged Products was to sell

those products. Those representations constituted commercial speech, not simply practicing religion or engaging in "charitable solicitations." See RRB at 62. As a matter of law, including religious or political views in the commercial advertising at issue does not convert Respondents' commercial speech to constitutionally protected religious or political speech. ID at 114; *see also Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 67-68 (1983) (holding that mailings constituted "commercial speech notwithstanding the fact that they contain discussions of important public issues such as venereal disease and family planning"); *id.* at 68 (*quoting Central Hudson*, 447 U.S. at 563 n.5 ("[A]dvertising which 'links a product to a current public debate' is not thereby entitled to the constitutional protection afforded noncommercial speech.")).

Accordingly, the Supreme Court cases concerning *non-commercial* speech upon which Respondents rely, – namely, *New York Times Co. v. Sullivan*, 376 U.S. 254 (1964); *Village of Schaumburg v. Citizens for a Better Environment*, 444 U.S. 620 (1980); and *West Virginia State Board of Education v. Barnette*, 319 U.S. 624 (1943) – do not apply at all. *Cf. Church of Scientology v. Richardson*, 437 F. 2d 214, 218 (9th Cir. 1971) (holding there was no First Amendment violation so long as the FDA "could determine the E-meter's [an instrument used in the practice of Scientology] intended use without evaluating the truth or falsity of any related 'religious' claims."). RRB at 56.

The Supreme Court's First Amendment cases involving commercial speech upon which Respondents rely – *Central Hudson*, 447 U.S. 557; *Edenfield v. Fane*, 507 U.S. 761 (1993); *Greater New Orleans Broadcasting Ass'n. v. United States*, 527 U.S. 173 (1999); *Ibanez v. Florida Department of Business & Professional Regulation, Board of Accountancy*, 512 U.S. 136 (1994); *In re R.M.J.*, 455 U.S. 191 (1982); *Peel v. Attorney Registration & Disciplinary Commission*, 496 U.S. 91 (1990); *Rubin v. Coors Brewery Co.*, 514 U.S. 476 (1995); *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002); *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976); and *Illinois ex rel. Madigan v. Telemarketers Ass'n.*, 538 U.S. 600, 619-20 (2003) – have all affirmed that misleading or deceptive commercial speech is not protected by the First Amendment. Those declarations are often included in the passages cited by Respondents. RAB at 18, 20-21; RRB at 51-52.

Respondents argue that *Central Hudson*, *Peel*, *Ibanez* and *Thompson*, *Madigan* and *Greater New Orleans Broadcasting* teach that under the First Amendment, the government (here the FTC) must identify a "substantial interest" in order to justify restricting their advertising. RAB at 20-23; RRB at 51-52. Respondents further cite *Edenfield*, 507 U.S. at 770-71, for the proposition that the "substantial interest" cannot be established by mere "speculation and conjecture." RAB at 22. But that gets things backward. In *Central Hudson*, the Supreme Court set

forth the four-part analysis for determining whether regulation of commercial speech is constitutional. A first and threshold inquiry is whether the speech in question is false or misleading; for commercial speech to be afforded any First Amendment protection, "it at least must concern lawful activity and not be misleading." 447 U.S. at 566. Non-misleading commercial speech remains subject to reasonable regulation, under the remaining three elements of the *Central Hudson* analysis: whether the regulation is based on a substantial governmental interest; "whether the regulation directly advances the governmental interest asserted;" and "whether it is not more extensive than necessary to serve that interest." *Id.*

The cases cited by Respondents all recognize that the latter three prongs of the test are reached if, and only if, Respondent's advertising is not misleading or deceptive. *See Edenfield*, 507 U.S. at 768 ("[O]ur cases make clear that the State may ban commercial expression that is fraudulent or deceptive without further justification."). The ALJ found Respondents' commercial speech deceptive. The record shows that the ALJ's findings were based on the text of the advertisements at issue, as well as the Respondents' use of testimonials, bold print, pictures and mutually reinforcing advertisements to create the "overall net impressions" conveyed by the advertisements. In reviewing the ALJ's findings, the Commission has also brought its expertise and experience to bear. Once reaching that finding, no further analysis is necessary.

Respondents also emphasize that *Thompson v. Western States Medical Center* held that under the First Amendment, even if the government has an interest in preventing misleading advertisements, it could not enjoin the compounding of drugs if disclaimers would be a less restrictive alternative. RAB at 60. In their Reply Brief, Respondents argue that *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), said the same thing about the use of disclaimers. RRB at 27-30. That case does not help Respondents either. Both in *Thompson* and in the portion of *Pearson* on which Respondents rely, the issue was not the condemnation of particular commercial speech found to have been actually misleading, but rather the regulation of broad categories of speech, subject to the latter three prongs of the *Central Hudson* analysis. *See Thompson*, 535 U.S. at 368; *Pearson*, 164 F.3d at 655-56. It was in the context of that analysis assessing the "fit" between government regulation of non-misleading commercial speech and the interests sought to be served – that each court focused on the use of disclaimers as a substantially less restrictive alternative to outright bans. *See Central Hudson*, 535 U.S. at 376; *Pearson*, 164 F.3d at 657-58. Respondents offer no support for their assertion that the *Central Hudson* "fit" analysis should be imported into cases like the present one, in which an administrative agency is adjudicating the deceptive nature of particular advertisements.[2]

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[2] Respondents further attempt to bootstrap from *Pearson*'s holding by equating the "potentially misleading" speech

(Continued on following page)

Even if we were to adopt Respondents' unprecedented approach to this issue, their arguments fail on the record before us. Respondents' "disclaimers" here were ineffective, given the multiple techniques Respondents used to reinforce their overall advertising messages, the comparatively small print in which most of their "disclaimers" were printed (IDF 296, 298, 299, 300, 303), their ambiguity and lack of conspicuousness (IDF 305), and the fact that even those "disclaimers" only disclaimed Respondents' "intentions," not the messages themselves. Any one of these factors would blunt the effectiveness of the disclaimers. *See, e.g., Removatron Int'l v. FTC*, 884 F.2d 1489, 1497 (1st Cir. 1989) (holding that disclaimer that was not clear and conspicuous was ineffective). Considering these factors in combination, Respondents' "disclaimers" did not dispel the overall net impressions that the four Challenged Products would treat or cure the diseases and conditions that Respondents' representations conveyed.

Second, Respondents argue that none of this First Amendment jurisprudence applies to herbal supplements like the four Challenged Products because they are not "drugs" within the meaning of the Food and Drug Act. RAB at 8. As Respondents

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subjected to prescriptive regulation there with the implied claims that have been specifically adjudicated in the present case to be actually misleading. RRB at 28. As explained above, however, the two are "completely different animal[s]." *Kraft*, 970 F.2d at 317.

acknowledge, the Food and Drug Act "differs from" the FTC Act. RRB at 41 (*quoting FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008)). Respondents do not explain why or how the Food and Drug Act can be considered binding on the Commission in enforcing the Sections 5 and 12 of the FTC Act. Under the FTC Act, these products are embraced within Section 5, and, as the ALJ observed, the FTC Act defines the words "food" and "drug" broadly for purposes of Section 12. ID at 80. Accordingly, the courts have repeatedly held that that definition covers dietary supplements. *See, e.g., FTC v. Natural Solution, Inc.*, No. CV 06-6112-JFW, 2007 U.S. Dist. LEXIS 60783, at *11-12 (C.D. Cal. Aug. 7, 2007); *Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *43-44; *Direct Mktg. Concepts*, 569 F. Supp. 2d at 300, 303; *see also* ID at 80-81, 103. Moreover, those same courts have specifically held that such products can be deceptive if they lack a reasonable basis substantiating the claims made for them. *Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *9-10; *Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *76-79; *Direct Mktg. Concepts*, 569 F. Supp. 2d at 298.

Third, Respondents repeatedly assert that the Commission cannot challenge their efficacy representations for the four Challenged Products because those representations were simply "structure/function" claims that are permitted under the Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4325 ("DSHEA"), which amended the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.

§§ 301-399a ("FDCA"). RAB at 3, 4, 12, 45, 46, 51, 52; RRB at 33, 40, 41, 45. Respondents' representations, however, are not "structure/function" claims under the DSHEA. Under the FDCA, such a claim is defined simply as one that describes "the role of a nutrient or dietary ingredient intended to affect the structure or function in humans." 21 C.F.R. § 101.93(f) (2009). The Respondents' representations that the four Challenged Products would treat or cure cancer, prevent or shrink tumors, and ameliorate the side effects of radiation and chemotherapy do not simply describe the "role" that those four products will play in affecting the structure or function in humans. *See United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 568 (D.N.J. 2004); *see also Pearson*, 164 F.3d at 652. Moreover, DSHEA expressly provides that even compliant "structure/function" claims are permitted only if they are "truthful and not misleading" and the manufacturer "has substantiation" that such claims are true. 21 U.S.C. § 343(r)(6)(B) (2009). Thus, the DSHEA amendment to the FDCA is not inconsistent with the FTC case law as applied by the ALJ. Indeed, even if the FDCA departed from the FTC Act and its relevant case law, Respondents offer no authority that it would be binding on the Commission.

Fourth, Respondents argue that the ALJ failed to adopt a "flexible standard of substantiation" for their representations and ignored numerous studies supporting those representations, contrary to the FTC's guidelines entitled, *Dietary Supplements: An Advertising Guide for Industry* ("Guide"). RAB at 47-48.

The Commission does not agree. The Guide advises the Commission's standard of substantiation for dietary supplements is "flexible," because the standard depends upon the claims made for those products. Guide at 8. The Guide warns that the "FTC typically requires claims about the efficacy or safety of dietary supplements to be supported with 'competent and reliable scientific evidence.' Guide at 9. Thus, where, as here, Respondents represented that the four Challenged Products would treat or cure cancer, prevent or shrink tumors, and/or ameliorate the destructive side effects of radiation or chemotherapy, the competent and reliable scientific standard applies under the Guide.

Fifth, Respondents maintain that they only intended to convey the impression that their "Biblical approach to health care – including use of the Challenged Products – could reinforce the naturally healing capability of the body, including the immune system, and thereby provide adjunct support for whatever path – drugs, surgery or other – an individual freely chose to take for their cancer care regimen." RAB at 44. That stated intent is at odds with almost all of the advertisements themselves, which generally did not mention the "naturally healing ability of the body" or that the four Challenged Products could be only an "adjunct" to traditional cancer treatments. But in any event, the courts have long held that "the subjective good faith of the advertiser is not a valid defense." *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1007

(N.D. Ill. 1998); *see also FTC v. World Travel Vacation Brokers, Inc.*, 861 F.2d 1020, 1029 (7th Cir. 1988).

Finally, Respondents contend that they cannot be held liable for deception because all of the elements of Section 5(n) of the FTC Act have not been proved. That is, Respondents argue Complaint Counsel failed to prove their acts were both unfair and deceptive. That argument is without merit. No case has ever held that deception claims are subject to Section 5(n).

D. Due Process Was Not Violated.

Despite Respondents' claims to the contrary, it cannot be said that the ALJ violated Due Process in reaching his findings of fact under a "preponderance of evidence" standard instead of a "clear and convincing evidence" standard. RAB at 11, 27-29. As the ALJ states in his Initial Decision, under both the Administrative Procedure Act and the Commission's rules, the proper standard to be applied in FTC Act cases challenging deceptive practices is the "preponderance of evidence" standard. ID at 66-67. Federal court and Commission decisions respecting those challenges have repeatedly so held. *In re Telebrands Corp.*, 140 F.T.C. 278, 426 (2004), *aff'd*, 140 F.T.C. 278 (2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006); *In re Auto. Breakthrough Sciences, Inc.*, No. 9275, 1998 FTC LEXIS 112, at *37 n.45 (Sept. 9, 1998); *In re Adventist Health System/West*, 117 F.T.C. 224, 297 (1994); *In re Bristol-Myers Co. v. FTC*, 102 F.T.C. 21, 275 (1983), *aff'd*, 738 F.2d 554 (2d Cir. 1984). Moreover, contrary

to Respondents' assertion in their Reply Brief (RRB at 47), those decisions do not simply concern the standard applicable to litigating over whether the FTC has jurisdiction. *Telebrands,* for example, concerned whether certain representations were conveyed in the advertising, and whether they were deceptive. 140 F.T.C. at 427, 449.

Other cases upon which the Respondents rely, *Addington v. Texas,* 441 U.S. 418 (1979); *Stanley v. Illinois,* 405 U.S. 645 (1972); and *Mathews v. Eldridge,* 424 U.S. 319 (1976) (RAB at 26-28), do not hold otherwise. Those cases did not consider the standard of proof applicable under the FTC Act or the standard of proof applicable when the FTC challenges deceptive acts or practices. Indeed, they are entirely inapposite. *Stanley* simply held that a State may not deprive an unwed father of custody of his children, on the basis of a statutory presumption of unfitness, but must afford an individualized fitness hearing. In the present case, Respondents have been afforded an extensive hearing on the specific charges against them. *Mathews* set forth general standards for due process procedures, but emphasized the flexibility of the constitutional standard. 424 U.S. at 334-35. The Court there upheld an administrative scheme for the termination of disability benefits without any pre-termination evidentiary hearing – a holding that offers the present Respondents no support. *Id.* at 339-40. In *Addington* – the only case cited that addresses a constitutional requirement regarding the standard of proof – the Supreme Court held that due process

requires "clear and convincing" evidence to support the indefinite, involuntary commitment of an individual to a mental institution. 441 U.S. at 431-32. The holding in *Addington,* respecting an extreme form of deprivation of personal liberty, has no bearing on the present case. Here, Respondents were afforded ample procedural protections, including adjudication under the established preponderance of evidence standard typical of civil litigation. Their assertions that due process required more than this are without merit.

E. There is No Reasonable Basis Substantiating the Representations.

Findings of Fact.

Respondents alleged in their Answer that they possessed and relied upon a reasonable basis that substantiated the representations they made for the four products at issue at the time those representations were made. Answer ¶ 16; RAB at 2. However, Respondents did not conduct or direct others to conduct any scientific testing of the effects of the four Challenged Products. IDF 308, 309, 311, 313, 315. The manufacturers of BioShark and BioMixx likewise did not conduct any testing on those products. IDF 310, 314. Respondents have not produced anything to show that they possessed and relied on any competent and reliable scientific evidence to support the overall net impressions conveyed by the advertisements at issue.

The ALJ considered the evidence presented by Complaint Counsel's expert, Dennis Miller, M.D. and Respondents' five experts, James Duke, Ph.D., Sally LaMont, N.D., Rustuna Roy, James Dews and Jay Lehr, Ph.D. IDF 329-425. The only proffered expert who was a medical doctor, had specialized training or experience regarding cancer or cancer treatment, or had conducted clinical studies regarding cancer treatments was Dr. Miller. IDF 329-337. Dr. Miller is a board-certified pediatric hematologist/oncologist who, *inter alia,* has directed clinical care, education, laboratory and clinical research, and administration heading divisions or departments for over forty years at the University of Rochester Medical Center, New York Hospital-Cornell Medical Center, Memorial Sloan-Kettering Cancer Center and Northwestern University Medical School. IDF 320-326.

Dr. Miller testified that "competent and reliable scientific evidence" is required to conclude that a cancer treatment is effective. IDF 343. Dr. Miller explained that in order to constitute competent and reliable scientific evidence that a product treats, cures, or prevents cancer, the products' efficacy and safety must be demonstrated through controlled clinical studies (tests on humans). IDF 344, 345. He further testified that studies performed in test tubes or in animals, testimonials and other anecdotal reports are not substitutes. IDF 345, 351-353. He testified that harm potentially may occur from remedies that are alternatives to those that have undergone clinical studies on humans. IDF 356-361. And,

he testified that for these reasons, the need to substantiate a claim by clinical studies (*i.e.*, on humans) was the same whether the purported agent was a herbal medicine or a more conventional pharmaceutical agent. IDF 354.

Dr. Miller was asked to determine whether there was competent and reliable scientific evidence to substantiate each of the overall net impressions conveyed by the advertisements at issue about the Challenged Products, and he did so. IDF 327, 344, 345, 351-354. Dr. Miller concluded that the reference materials relied on by Respondents did not constitute competent and reliable scientific evidence that any of the Challenged Products prevent, treat or cure cancer; that most of those materials were not peer-reviewed papers but instead consisted of author opinions and literature reviews; that many of the studies involved *in vitro* or animal studies, not studies on humans; that others relied on the efficacy or safety of ingredients of the Challenged Products rather than the products themselves and that, absent, evidence that DCO's four products at issue here contained exactly those ingredients in the proportion tested, those studies were not probative; and that there is no competent and reliable scientific evidence that the Challenged Products are effective, either alone or in combination with other DCO products, in the prevention, treatment or cure of cancer, in inhibiting tumor formation, or in ameliorating the adverse effects of radiation and chemotherapy. IDF 362-367. The reference materials on which Respondents relied

were of the sort that Dr. Miller testified were not reliable. IDF 368-386.

Respondents did not ask any of their proffered experts to render an opinion as to whether Respondent's purported substantiation materials constituted competent and reliable scientific evidence substantiating any of the overall net impressions conveyed by the advertisements at issue about the Challenged Products. IDF 339. Neither did Respondents ask any of their proffered experts to render an opinion as to whether there existed any such substantiating evidence. IDF 340. Respondents' expert, Dr. Duke, made no effort to determine whether there were any studies of any sort regarding the Challenged Products; he did not analyze any of those products; and he did not know the ingredients of those products. IDF 392-394. Dr. LaMont likewise did not analyze any of the Challenged Products themselves, but only the ingredients in those products, and she did not know the concentration of those ingredients in those products. IDF 401-403. Mr. Roy did not review or obtain any of the Challenged Products or their labels, and he had no idea what ingredients those products contain. IDF 412, 413. None of the experts proffered by Respondents expressed any opinion about whether there was any competent and reliable scientific evidence to support the overall net impressions respecting the efficacy of the four products at issue created by the challenged advertisements. IDF 341, 389, 390, 398, 399, 408, 409, 419, 420, 423, 424.

Legal Analysis.

Respondents have repeatedly accused the ALJ of improperly engaging in "presumptions," "shifting the burden of proof" away from Complaint Counsel, as well as violating the Due Process Clause and the First Amendment of the Constitution. Thus, in reviewing the ALJ's conclusion that Respondents lacked a reasonable basis substantiating their representations concerning the efficacy of the Challenged Products, it is appropriate to analyze what the ALJ did not do, in addition to what he did do.

First, the ALJ did not treat Respondents' advertising as making "establishment" claims – that is to say, advertising that represents the amount and type of evidence substantiating the product claims made. ID at 100-101. Although the ALJ pointed out that a few of the advertisements did represent that the claims had been proven by scientific testing (ID at 101 (citing IDF 225, 231, 247)), he concluded, "Complaint Counsel has not alleged or argued that Respondents' advertisements constitute establishment claims. Accordingly, the claims at issue are deemed non-establishment claims, and will be evaluated as such." ID at 101.

The result of that conclusion, however, is that in determining the level of substantiation required, the ALJ did not "presume" the truth of Respondents' representations that their claims were supported by a study conducted by "two researchers at the Massachusetts Institute of Technology" or "used by patients

involved in clinical studies in cancer clinics." IDF 225 (CX 13); IDF 231 (CX 23 & 24); IDF 247 (CX 18). Instead, the ALJ found the claims to be "health-related efficacy claims," and as a result, under well-established precedent, such claims must be substantiated by "competent and reliable scientific evidence." ID at 101. In addition, to the extent that further analysis for determining the substantiation standard was necessary, the ALJ also analyzed them under the *Pfizer* factors: the type of claim involved, the benefits of a truthful claim, the consequences of a false claim, and the amount of substantiation experts in the field consider reasonable. ID at 102-104; *In re Pfizer, Inc.*, 81 F.T.C. 23 (1972); *QT, Inc.*, 448 F. Supp. 2d at 959; *Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *43-44, 77-79; *In re Removatron*, 111 F.T.C. 206, 306 n.20 (1988); *In re Thompson Med. Co.*, 104 F.T.C. at 821.

Based upon his findings respecting the "overall net impressions" conveyed by Respondents' representations, the ALJ concluded that: (1) the representations made about the four Challenged Products were "health-related efficacy claims" in that they represented that the products would "treat or cure" cancer, eliminate or shrink tumors, and/or ameliorate the adverse effects of radiation and chemotherapy (ID at 101-102); (2) the benefits of truthful claims were substantial because cancer patients would benefit from truthful representations about effective treatment of, or cure for, the disease (ID at 103); (3) the consequences of a deceptive claim were substantial

not only because a patient might forego using products or therapies that were effective in treating or curing the relevant diseases, but also (as Respondents acknowledged in their "disclaimers"), because their products could be harmful if used with the other products or therapies (ID at 103); and (4) clinical studies respecting human beings were required because the representations Respondents made concerned the efficacy of the Challenged Products in treating or curing human beings, not animals, or their efficacy in vitro. ID at 103-104.

Taking those considerations into account, the ALJ concluded that Respondents' representations needed to be substantiated by "competent and reliable scientific evidence," including "controlled clinical studies" – *i.e.*, human studies. ID at 104. That conclusion is supported by numerous decisions describing the standard that should be applied when supplements like the Respondents' four products are represented to be effective to treat diseases or medical conditions. *See, e.g.*, *Natural Solution*, 2007 U.S. Dist LEXIS 60783, at *11-12; *Nat'l Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *43-44; *Direct Mktg. Concepts*, 569 F. Supp. 2d at 300, 303.

Second, the ALJ did not hold Respondents to the representation they made in their Answer that they had a reasonable basis substantiating their representations at the time the representations were made. The only explanation that the ALJ articulated for not requiring Respondents to tether their proof to "the time the representations were made" was that

Complaint Counsel, rather than Respondents, had the burden of proof on all elements of their claim, including whether Respondents had a reasonable basis to substantiate their representations. ID at 67. The Commission considers that conclusion debatable. Respondents specifically averred that they had substantiation at the time their representations were made, and they were in the best position to support their averment. Again, the Commission is not prepared to second-guess the decision by the ALJ. The consequence of that conclusion, however, was that the ALJ considered abundant *ex post* expert testimony on the issue whether there was *ever* a reasonable basis substantiating the representations.

Respondents repeatedly assert that in assessing the expert testimony the ALJ did not just embrace the substantiation standard he had held was applicable – namely "competent and reliable scientific evidence," including "controlled clinical studies" – but instead required that those studies be "double-blind" and "placebo controlled." RAB at 4, 8, 11-12, 15, 25, 43, 45; RRB at 12, 40-41, 53-54, 57, 59, 65. According to Respondents, that substantiation requirement, combined with the lack of a requirement that "extrinsic evidence" be produced, had the effect of creating a "presumption" that their representations were not adequately substantiated and, indeed, of turning the proceeding into "rulemaking by adjudication" in violation of *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), the Due Process Clause, and the First

Amendment of the Constitution. RAB at 4, 11-12, 15-17, 25-26, 43-44, 54-55; RRB at 40, 54-55.

Respondents' claims are without merit. As previously discussed, "extrinsic" evidence to interpret the advertising is not required, as a matter of law. Respondents' reliance on *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008), does not assist their argument either. As the ALJ explained in the Initial Decision, although the Seventh Circuit stated that nothing in the FTC Act required a placebo-controlled, double-blind study, it went on to affirm the district court's holding that substantiation for health-related efficacy claims must be based on competent and reliable scientific evidence. ID at 109. Because the ALJ in this case found the Respondents had not possessed or relied upon *any* adequate substantiation for their claims, the ALJ found their argument that *QT* does not require a placebo-controlled, double-blind study to be irrelevant. ID at 109. The Commission agrees.

The same thing is true of Respondents' assertion that this case involves "rulemaking by adjudication" of the sort condemned in the *Pearson* case. RAB at 15-16, 25-26; RRB at 27, 3133, 44 n.24, 53-54. *Pearson* bears no resemblance to this case. Not only were the agency (the FDA) and the statute (the Food, Drug, and Cosmetic Act) different than the ones involved here, but the case involved formal rulemaking procedures by the FDA. In *Pearson*, the FDA proposed a rule that would ban all health claims by dietary supplements unless there was "significant scientific agreement" about those claims, regardless

of whether or not the claims were deceptive. RAB at 14-16. This case does not involve rule-making or even "amending or bypassing a pending rulemaking proceeding." RAB at 40. This case involves a purely adjudicatory challenge to specific deceptive representations made in advertisements that four specific products would "treat" or "cure" cancer, prevent or shrink tumors, and ameliorate the destructive side effects of radiation or chemotherapy. Most significantly, the substantiation standard used by the ALJ in this case, requiring competent and reliable scientific evidence, including studies on humans is neither "unconstitutionally vague" nor "impossibly high," as Respondents describe the "significant scientific agreement" standard in the FDA's proposed rule. RRB at 27, 31-32, 44 n.24. To borrow the language in *Kraft*, *Pearson* involved "a completely different animal" than the one involved here. *Kraft*, 970 F.2d at 317.

Nor did the ALJ otherwise use any "assumptions" or "shift the burden of proof" away from Complaint Counsel in his assessment of the expert testimony. RAB at 3, 11, 54-55. To the contrary, he found, *inter alia*, that Complaint Counsel's witness, Dr. Miller, a board-certified oncologist who had practiced for over forty years at some of the country's most eminent institutions, was the "only witness in this case qualified as an expert in cancer research and cancer treatment" (ID at 103), and that he was the only expert witness who offered an opinion as to whether there was competent and reliable scientific evidence

to support Respondents' representations. ID at 103-106. By contrast, the ALJ found that Respondents and their experts had relied, *inter alia*, on in vitro and animal (not human) clinical reports, searches of literature, testimonials without confirmation that the speakers' treatments were not attributable to other clinical modalities or indeed that the speakers had cancer, and tests on the ingredients of the four Challenged Products without confirmation that the ingredients were present in those products in the same proportion to the ingredients tested. ID at 104-105.

Respondents do not contend that these findings lacked substantial supporting evidence in the record. As a result, as the ALJ put it, "none of Respondents' experts offered any opinions on any material, contested issue in the case, and the opinions that Respondents' proffered experts did offer are entitled to little, if any, weight." ID at 106. Put differently, the ALJ simply weighed the evidence proffered by the experts. The way he weighed the evidence, moreover, was consistent with his earlier opinion that although Respondents might have the burden of production of some evidence to substantiate their representations, Complaint Counsel bore the burden of proving that the substantiation was inadequate. ID at 67. The ALJ concluded that Complaint Counsel had borne the burden of proving that Respondents' representations were not substantiated. There was no violation of either the Due Process Clause or the First Amendment involved.

F. The Remedy is Proper.

Respondents advance several arguments that the remedy is illegal. RAB at 55-65. The Commission has considered each of these arguments, has reviewed the applicable case law and the language of the proposed Order, and has concluded that these claims are without merit. The Commission considers each of these arguments in turn.

Respondents first argue that the recent unpublished decision in *FTC v. Lane Labs-USA, Inc.*, No. 00-CV-3174 (DMC) (D.N.J. Aug. 10, 2009) (appeal pending),[3] "should be instructive and considered here," (RAB at 56-57; *see also* RRB at 59-60), and that they are "identically situated" to the respondents in *Lane Labs*. RRB at 34. In doing so, Respondents focus on three statements made by the district court, which were based upon the specific facts and evidence presented in that case: 1) the district court considered the substantiation proffered by Lane Labs and noted, "[t]his is not a case of a company making claims out of thin air;" 2) the district court found that Lane Labs provided credible medical testimony that the products in question are good products and could have the results advertised; and 3) the district court noted that "there has been no physical harm to the public."

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[3] The Commission is appealing this decision. *FTC v. Lane-Labs-USA, Inc.*, No. 00-CV3174 (DMC) (D. N.J. Aug. 10, 2009), *appeal docketed*, No. 09-3909 (3rd Cir. Oct. 13, 2009).

Contrary to Respondents' assertion, they are not "identically situated" to the respondents in *Lane Labs*. *Lane Labs* was a civil contempt proceeding in which the FTC sought a $24 million compensatory contempt award from the defendants for violating a negotiated consent order. According to the district court, in order to establish contempt, the movant bears the burden of proving by clear and convincing evidence that the respondent violated a court order. *Lane Labs*, No. 00-CV-3174 (DMC), slip op. at 11. The district court declined to find contempt because he found that the FTC failed to show by clear and convincing evidence that the defendants had not substantially complied with the Orders. Accordingly, the standard of proof, as well as the proof required, differentiates the DCO Respondents from the Lane Lab respondents.

And, to the extent that *Lane Labs* – as an unpublished decision that is being appealed – can be considered "instructive," it does not help Respondents. As in the instant case, the *Lane Lab* Orders required defendants to possess "competent and reliable scientific evidence" (as defined in the DCO remedy) to substantiate any claims made about the health benefits of a product.[4] The *Lane Labs* court

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[4] "Competent and scientific evidence" was defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the

(Continued on following page)

specifically found the Orders to be valid and controlling. *Id.* at 12. However, in contrast to the case before us, the medical experts proffered in *Lane Labs* were medical doctors that the district court qualified and found "credible and knowledgeable in their respective fields of expertise." *Id.* at 8-10. The DCO respondents' experts were not medical doctors and the ALJ found that none of these proffered experts had "specialized training or experience regarding cancer or cancer treatment." IDF 335, 336. Indeed, in contrast to *Lane Labs*, in preparing their opinions, none of Respondents' experts here had reviewed the advertising claims at issue. IDF at 338. Furthermore, Respondents did not ask their experts to render an opinion as to whether their purported substantiation materials constituted competent and reliable scientific evidence that would substantiate a claim that any of the Challenged Products prevent, cure or treat, cancer (IDF 339), or whether any such evidence existed. IDF 340.

Second, Respondents argue that the remedy is an arbitrary, capricious and retaliatory attack on their constitutional rights. Respondents make many general allegations regarding this claim, but do not cite any case law or other precedent in support of it. Respondents assert that the ALJ used "Respondents' political and religious speech as a weapon against

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profession to yield accurate results." *Lane Labs*, slip op. at 12. This is the same definition the ALJ uses in the proposed Order.

them when he turned to issuing the Remedy." RRB at 36; *see also* RAB at 57. Respondents also claim that the ALJ took the Respondents' political and religious speech and activities into consideration when crafting the remedy, but not when "portraying Respondents as being engaged purely in commerce." RAB at 57.

As a preliminary matter, the Commission notes that the ALJ did not "portray[ ] Respondents as being engaged purely in commerce." As the Commission has stated already, this misstates the law and the legal conclusions of the Initial Decision; the ALJ found that Respondents were not a business organized for or engaged in "only" charitable purposes. These two conclusions are not the same. In addition, as discussed earlier in this Opinion, the Commission has already found that the ALJ performed the proper legal analysis in determining the FTC's jurisdiction, *see* section III.A, and Respondents' liability, *see* sections III.C and E. The Commission likewise finds that the ALJ applied the proper standard in drafting the proposed order.[5] Accordingly, the Commission declines

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[5] Once the determination is made that Respondents violated Section 5 of the FTC. Act, the Commission has the authority to issue an order requiring respondents to cease and desist from such acts and or practices. *FTC v. Nat'l Lead Co.*, 352 U.S. 419, 428 (1957). The Commission has considerable discretion in fashioning the remedial order, so long as the order bears a reasonable relationship to the unlawful acts or practices. *See, e.g., FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 394-95 (1965); *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 612-13 (1946).

to characterize the remedy as "arbitrary, capricious and retaliatory."

Third, Respondents claim that the proposed remedy would violate the Religious Freedom Restoration Act of 1993 (P.L. 10-141) ("RFRA"). RAB at 57-60. The Commission disagrees. As Respondents concede, the RFRA only applies to government statutes that "substantially burden a person's exercise of religion." RAB at 58; RRB at 15, 60-61. The Order imposes no burden on Respondents' exercise of religion; it only applies to their commercial advertising. Although Respondents argue the remedy imposes an unconstitutional prior restraint on "truthful speech," (RAB at 61; RRB at 60-63), the speech at issue here was found to be deceptive. As noted in *Central Hudson*, "there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity." 447 U.S. at 563.

Far from prohibiting truthful speech, Paragraphs II and III of the Order permit Respondents to make any efficacy claims for those products so long as the representations are "true, non-misleading, and, at the time [they are] made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation." In other words, Respondents are only obliged to do that which the case law under Sections 5 and 12 of the FTC Act has defined as necessary to avoid deception. To be sure, that requirement embraces not just the four Challenged Products, but other dietary supplements, foods, drugs or other health and related programs,

services or products. However, the case law holds that this is appropriate "fencing in," given the kinds of representations Respondents made and the frequency with which they made those representations. *Telebrands Corp. v. FTC,* 457 F.3d 354, 358 (4th Cir. 2006); *Kraft,* 970 F.2d at 326.[6] The proposed order limits what Respondents may say without substantiation relating to the sale of certain products, but it does not otherwise reach into the Respondents' religious speech or practices.

Finally, Respondents claim that the requirement that they send a letter to their customers – even as modified by the ALJ – would unconstitutionally encroach on their rights under the religious guarantees of the First Amendment and the RFRA. RAB at 61-65; RRB at 63. Specifically, Respondents claim that the proposed remedy "prohibits truthful speech," is "contrary to Mr. Feijo's right to refrain from speaking at all," forces Respondents "to repudiate publicly

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[6] The Commission generally considers three factors in determining whether an order bears a reasonable relationship to a particular violation: (1) the seriousness and deliberateness of the violation; (2) the ease with which the violation may be transferred to other products; and (3) whether the respondent has a history of prior violations. *See In re Stouffer Foods Corp.,* 118 F.T.C. 746, 811 (1994). All three elements need not be present to warrant fencing-in. *See Sears, Roebuck & Co. v. FTC,* 676 F.2d 385, 392 (9th Cir. 1982). The ALJ considered these factors and found the relief ordered was reasonably related to the Respondents' violations of the FTC Act. Respondents do not seem to challenge the ALJ's analysis of these elements. ID at 120-21.

their faith in God's revealed truth and be forced to embrace and proclaim as their own the FTC's faith in so-called 'science'," and "compels Respondents to conduct government-mandated speech as a condition precedent to continuing their religious ministry." RAB at 12, 57-64; RRB at 58, 64.

Paragraph V of the Order requires Respondents to send to all consumers who have bought the four Challenged Products since the beginning of 2005 an exact copy of the letter appended to the Order as Attachment A. The ALJ modified the proposed letter attached to the Complaint "to make it clear that the information contained in the letter is information that the FTC has required Respondents to transmit to consumers." ID at 121. Neither the letter nor anything else in the Order compels Respondents to do anything "as a condition precedent to continuing their religious ministry," or forces Respondents to "repudiate publicly 'their faith' in God's revealed truth and be forced to endorse and proclaim as their own the FTC's faith in so-called 'science.'" RRB at 58. Neither does the Commission see any evidence that the ALJ punished Respondents for their political or religious beliefs in his proposed order.

However, in the Order the Commission issues here today, in the interest of brevity, the Commission has further modified the first and second paragraphs of the letter required by Paragraph V (appended to the Order as Attachment A).

IV. Conclusion

The Commission, for the reasons stated in this opinion, has determined to deny the appeal of Respondents and to make final the attached Order, which is identical to the order entered by the ALJ, except as to the modifications made to Attachment A, the letter required to be sent to consumers by Respondents.

PUBLIC

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

DOCKET NO. 9329

In the Matter of

DANIEL CHAPTER ONE
a corporation, and

JAMES FEIJO,
individually, and as an
officer of Daniel Chapter One

Respondents.

INITIAL DECISION

D. Michael Chappell
Chief Administrative
Law Judge

Date: August 5, 2009

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I. INTRODUCTION

A. Summary of Complaint and Answer

The Federal Trade Commission ("FTC") issued the Complaint in this matter on September 16, 2008 against Daniel Chapter One ("DCO") and James Feijo ("Respondents"). The Complaint alleges that Respondents have engaged in deceptive acts or practices in connection with the advertising, promotion, offering for sale, sale, and distribution of four products: BioShark, 7 Herb Formula, GDU, and BioMixx (collectively, the "Challenged Products"). Complaint ¶ 3. The Complaint also alleges that Respondents operate linked web pages on the website, www.daniel chapterone.com, through which they advertise and sell the Challenged Products. Complaint ¶ 5.

The Complaint alleges that the Challenged Products are advertised to prevent, treat, or cure

cancer or tumors, Complaint ¶ 5, and specifically charges that the advertisements represent, expressly or impliedly, that:

> Bio*Shark inhibits tumor growth;
> Bio*Shark is effective in the treatment of cancer;
> 7 Herb Formula is effective in the treatment or cure of cancer;
> 7 Herb Formula inhibits tumor formation;
> GDU eliminates tumors;
> GDU is effective in the treatment of cancer;
> BioMixx is effective in the treatment of cancer; and
> BioMixx heals the destructive effects of radiation and chemotherapy.

Complaint ¶ 14. The Complaint further alleges that Respondents represented, either expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the claims made, but that Respondents did not, in fact, possess and rely upon such reasonable basis. Complaint ¶¶ 15, 16. The Complaint charges Respondents with unfair or deceptive acts or practices, in or affecting commerce, in violation of Sections 5(a) and 12 of the Federal Trade Commission Act ("FTC Act"). Complaint ¶ 17.

In their Answer, filed on October 11, 2008, Respondents admit that they operate a website that provides information on the Challenged Products in a religious and educational context, but otherwise deny allegations that they engaged in deceptive acts or practices in connection with the advertising or sale of

the Challenged Products. Answer ¶ 5. Respondents averred that they did possess and rely upon a reasonable basis that substantiated the representations made about the Challenged Products at the time the representations were made. Answer ¶ 16.

Respondents' Answer also asserted six affirmative defenses. By stipulation of the parties, in an Order entered by the Administrative Law Judge ("ALJ") on January 8, 2009, the six affirmative defenses raised by Respondents in their Answer were stricken. On February 11, 2009, Respondents filed a motion to amend the Answer through which they sought to amend paragraphs 3, 5, and 14 of their Answer. The motion was opposed by Complaint Counsel. By Order dated March 4, 2009, Respondents' motion to amend was denied on the grounds that the proposed amendments would not facilitate a determination of a controversy, were not necessary to avoid prejudicing Respondents, did not conform to the evidence, and, coming after the close of discovery and approximately two months before trial, would have been unduly prejudicial to Complaint Counsel.

On February 25, 2009, Respondents filed a second motion to amend their answer, this time to add an affirmative defense that the Commission, in filing the Complaint and seeking the Cease and Desist Order included with the Complaint, was substantially burdening Respondents' free exercise of religion in violation of the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb-1(a) and (c). Complaint Counsel opposed the motion. By Order dated March

9, 2009, Respondents' motion to amend was denied on the grounds that the proposed amendment would not facilitate a determination of a controversy, and, coming after the close of discovery and approximately two months before trial, would have been unduly prejudicial to Complaint Counsel.

B. Procedural History

Respondents filed their first motion to dismiss on January 13, 2009, in which they contended, among other things, that the FTC has no jurisdiction over Respondents because DCO is a nonprofit religious ministry, not a commercial enterprise. Complaint Counsel opposed the motion. By Order dated February 2, 2009, the first motion to dismiss was denied on the grounds that Respondents had made a facial attack on the Complaint and that an evaluation of the allegations of the Complaint, which must be and were taken as true on such a motion to dismiss, sufficiently provided a basis for jurisdiction.

On February 13, 2009, Respondents filed a motion to reconsider the Order Denying Respondents' Motion to Dismiss Complaint. The motion was opposed by Complaint Counsel. By Order dated February 23, 2009, Respondents' motion was denied on the ground that Respondents failed to meet their burden for reconsideration.

Respondents filed a second motion to dismiss on February 25, 2009, in which Respondents again challenged the FTC's jurisdiction, arguing, among other

things, that DCO is a nonprofit religious ministry. The second motion to dismiss referenced evidence outside the Complaint and thus was not a facial attack that could be decided only on the allegations of the Complaint. Complaint Counsel opposed the motion. On February 25, 2009, Respondents also filed a motion for summary decision. Complaint Counsel, too, filed a motion for summary decision on February 25, 2009. Both motions were opposed. By Order dated March 20, 2009, it was held that Respondents' second motion to dismiss and both parties' motions for summary decision could not properly be resolved prior to a determination of whether the FTC has jurisdiction over Respondents. Accordingly, those motions were held in abeyance until after the conclusion of a hearing on jurisdiction.

On March 20, 2009, an order was issued setting an evidentiary hearing and oral argument to determine jurisdiction under Sections 4 and 5 of the FTC Act. 15 U.S.C. §§ 44, 45. The FTC Act gives the Commission authority over "persons, partnerships, or corporations," 15 U.S.C. § 45(a)(2), and defines "corporation" to include "any company . . . or association, incorporated or unincorporated, without shares of capital or capital stock or certificates of interest, except partnerships, which is organized to carry on business for its own profit or that of its members." 15 U.S.C. § 44.

The hearing on jurisdiction was held on April 21, 2009. Following the conclusion of that hearing, a ruling was issued from the bench that Complaint

Counsel had demonstrated, by a preponderance of the evidence, that jurisdiction does exist in this case. Respondents' second motion to dismiss and both parties' motions for summary decision were denied, as stated on the record in open court. Transcript of April 22, 2009 Final Pre-Hearing Conference, 4-6.

Respondents, on April 23, 2009, filed a motion for a Rule 3.23(b) determination authorizing Respondents to immediately appeal the denial of Respondents' motion to dismiss for lack of jurisdiction. Complaint Counsel opposed this motion. By Order dated May 5, 2009, that motion was denied on the ground that Respondents failed to satisfy any of the three prongs of the stringent three-prong test for interlocutory appeal.

Following the hearing on jurisdiction, the final pre-hearing conference was held on April 22, 2009, with trial commencing immediately thereafter. Over seventy exhibits were admitted and eleven witnesses testified at the hearing on jurisdiction and at trial. The testimonial portion of the trial concluded on April 27, 2009. On May 28, 2009, the parties filed concurrent post-trial briefs, proposed findings of fact, and proposed conclusions of law. The parties filed concurrent replies to each other's briefs and proposed findings on June 11, 2009. Closing arguments were heard on July 9, 2009.

The hearing record was closed, pursuant to Commission Rule 3.44(c), by Order dated May 7, 2009. Rule 3.51(a) of the Commission's Rules of Practice

states that an Initial Decision shall be filed "within ninety (90) days after closing the hearing record pursuant to § 3.44(c) . . . or within such further time as the Commission may by order allow upon written request from the Administrative Law Judge." 16 C.F.R. § 3.51(a). Ninety days from the close of the record is August 5, 2009.

Commission Rule 3.51(a) also states that an Initial Decision shall be filed within one year "after the issuance of the administrative complaint, except that the Administrative Law Judge may, upon a finding of extraordinary circumstances, extend the one-year deadline for a period of up to sixty (60) days." 16 C.F.R. § 3.51(a). The Complaint in this matter was issued on September 16, 2008. One year from the issuance of the Complaint is September 16, 2009.

C. Evidence

This Initial Decision is based on the exhibits properly admitted into evidence, the transcripts of testimony at the hearing on jurisdiction and at trial, and the briefs and proposed findings of fact and conclusions of law, and the replies thereto, submitted by the parties. Citations to specific numbered findings of fact in this Initial Decision are designated by "F."[1]

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[1] References to the record are abbreviated as follows:

CX – Complaint Counsel's Exhibit

R – Respondents' Exhibit

JX – Joint Exhibit

(Continued on following page)

Under Commission Rule 3.51(c)(1), "[a]n initial decision shall be based on a consideration of the whole record relevant to the issues decided, and shall be supported by reliable and probative evidence." 16 C.F.R. § 3.51(c)(1); *see In re Chicago Bridge & Iron Co.*, No. 9300, 138 F.T.C. 1024, 1027 n.4, 2005 FTC LEXIS 215, at *3 n.4 (Jan. 6, 2005). Under the Administrative Procedure Act ("APA"), an ALJ may not issue an order "except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence." APA, 5 U.S.C. § 556(d). All findings of fact in this Initial Decision are supported by reliable, probative, and substantial evidence.

HOJ Tr. – Transcript of Testimony from the Hearing on Jurisdiction
Tr. – Transcript of Testimony before the ALJ
Dep. – Transcript of Deposition
CC Juris. Br. – Complaint Counsel's Pre-Hearing Brief on Jurisdiction, April 13, 2009
R Juris. Br. – Respondents' Pre-Hearing Memorandum on Jurisdiction, attached to Respondents' April 14, 2009 Errata
CCB – Complaint Counsel's Post-Hearing Brief
RB – Respondents' Post-Hearing Brief
RCOL – Respondents' Conclusions of Law
RFF – Respondents' Proposed Findings of Fact
RRFF – Respondents' Response to Complaint Counsel's Proposed Findings of Fact

All testimony and exhibits from the hearing on jurisdiction are part of the record for the hearing on the merits. HOJ Tr. 13.

This Initial Decision is based on a consideration of the whole record relevant to the issues and addresses the material issues of fact and law. Ruling upon a decision of another Commission, and interpreting almost identical language to that in Commission Rule 3.51(c)(1) in the APA, the U.S. Supreme Court held that "[b]y the express terms of [that Act], the Commission is not required to make subordinate findings on every collateral contention advanced, but only upon those issues of fact, law, or discretion which are material." *Minneapolis & St. Louis Ry. Co. v. United States*, 361 U.S. 173, 193-94 (1959). *Accord Stauffer Labs., Inc. v. FTC*, 343 F.2d 75, 89 (9th Cir. 1965). *See also Borek Motor Sales, Inc. v. National Labor Relations Bd.*, 425 F.2d 677, 681 (7th Cir. 1970) (holding that it is adequate for the Board to indicate that it had considered each of the company's exceptions, even if only some of the exceptions were discussed, and stating that "[m]ore than that is not demanded by the [APA] and would place a severe burden upon the agency"); *In re Amrep Corp.*, No. 9018, 102 F.T.C. 1362, 1670, 1983 FTC LEXIS 17, *566-67 (Nov. 2, 1983) (the Administrative Law Judge is not required to discuss the testimony of each witness or each exhibit presented during the administrative adjudication).

Accordingly, proposed findings of fact that are not included in this Initial Decision were rejected, either because they were not supported by the evidence, or because they were not dispositive or material to the determination of the allegations of the Complaint or

the defenses thereto. Similarly, legal contentions and arguments not addressed in this Initial Decision were rejected, because they lacked support in fact or law, were not material, or were otherwise lacking in merit. All contentions and arguments in the parties' post trial-briefs and reply briefs were reviewed and considered.

D. Summary of the Initial Decision

As set forth in this Initial Decision, the record indicates that DCO, described by Respondents as a house ministry, led by Respondent James Feijo, with his wife Patricia Feijo, engaged in business for profit for itself or for its member, James Feijo. DCO's activities include spiritual and nutritional counseling to individuals, and advertising and selling dietary supplements to the public. Respondents sell four products at issue in the Complaint: BioShark, 7 Herb Formula, GDU, and BioMixx.

The evidence shows that Respondents disseminated advertisements for the purpose of inducing, and which did induce, the purchase of a food or drug, in or having an effect on commerce, and that these advertisements claim that the Challenged Products, individually or collectively, prevent, treat, or cure cancer, inhibit tumors, or ameliorate the adverse effects of radiation and chemotherapy. The evidence further shows that Respondents did not have a reasonable basis to substantiate these claims and that the claims made are material to consumers.

Complaint Counsel has carried its burden of proving that Respondents are liable under Sections 5(a) and 12 of the FTC Act. The defenses raised by Respondents have been considered and are determined to be without merit. The remedy imposed is an appropriate cease and desist Order.

II. FINDINGS OF FACT

A. Respondents

1. Daniel Chapter One and James Feijo

1. Respondent Daniel Chapter One ("DCO") is a corporation sole organized in 2002 under the laws of the State of Washington. (Respondents' Answer to FTC's Complaint, Oct. 14, 2008 (hereinafter referred to as Answer) ¶ 1; Complaint Counsel's Trial Exhibit (hereinafter referred to as CX ___) 31; J. Feijo, Hearing on Jurisdiction Transcript, Apr. 21, 2009, (hereinafter referred to as HOJ Tr. ___) 84).

2. DCO's Articles of Incorporation list the registered agent and incorporator for DCO as Rita Johnson and list her mailing location as P.O. Box 110788, Tacoma, Washington, 98411, non-domestic. (CX 31).

3. DCO's Articles of Incorporation list DCO's mailing address and principal location as James Jesse Feijo, c/o 21916 Southeast 392nd Street, Enumclaw, Washington, 98022, non-domestic. Neither Respondent DCO nor Respondent

James Feijo maintains a building at that address. (CX 31; J. Feijo, HOJ Tr. 93-95).

4. DCO's principal office and place of business are located at 1028 East Main Road, Portsmouth, Rhode Island 02871. (Answer ¶ 1; Deposition of James Feijo, Jan. 13, 2009 (hereinafter referred to as R 15 (J. Feijo, Dep. at ___)) at 99).

5. Respondent James Feijo is the overseer of DCO and, in this capacity, is responsible for all of the activities of Respondent DCO. (Answer ¶ 2; R 15 (J. Feijo, Dep. at 9-10, 17); J. Feijo, HOJ Tr. 70, 217; J. Feijo, Trial Transcript (hereinafter referred to as Tr. ___) at 416).

6. James Feijo is the trustee for DCO's assets and for all of the funds held by DCO. He is responsible for paying all of DCO's bills and directing DCO's funds. (J. Feijo, HOJ Tr. 72-73; R 15 (J. Feijo, Dep. at 9-10, 193, 198)).

7. Patricia Feijo is Respondent James Feijo's wife and is the secretary for DCO. James and Patricia Feijo are the only officers of DCO. (Answer ¶ 2; CX 39 (Respondents' Answer to Interrogatory No. 1); J. Feijo, HOJ Tr. 209; P. Feijo, HOJ Tr. 259, 276).

2. Overview of Respondents' activities

8. Respondents currently sell 150 to 200 products ("DCO products"), including the four products challenged in the Complaint: BioShark, 7 Herb Formula, GDU, and BioMixx (collectively, the "Challenged Products"). (R 15 (J. Feijo, Dep. at

37); P. Feijo, Tr. 392; Marino, HOJ Tr. 53-54; J. Feijo, HOJ Tr. 314-15).

9. Respondents have generated approximately $2 million in annual gross sales for the years 2006, 2007, and 2008 for all of DCO's nearly 200 products. (CX 44; R 15 (J. Feijo, Dep. at 206-07, 212); J. Feijo, HOJ Tr. 109, 223-24).

10. At present, 100% of DCO's product sales or distribution is dietary supplements. (J. Feijo, Tr. 419-20).

11. In 1983, DCO began as what James Feijo described as a house church – a church operating not in the typical sense that people think of, with a building, sign, and established doctrines, but as a church that meets in houses to worship and break bread, with no set times for religious meetings. (J. Feijo, HOJ Tr. 180-82, 263-64).

12. In 1986, DCO opened a health food store and began selling food sources. DCO began selling dietary supplements within the first year. (J. Feijo, Tr. 417-19).

13. In the mid-1990s, DCO began to develop its own dietary supplements and created BioMixx, before creating BioShark, 7 Herb Formula, and GDU, which Respondents created after 1993. (J. Feijo, Tr. 421, 423-24).

14. In 1998, Respondents created the website "danielchapterone.com" (hereinafter the "DCO Website"). (R 15 (J. Feijo, Dep. at 202)).

15. Around 1999, Respondents created the "BioGuide" and the "Cancer Newsletter" (*see infra* F. 86, 94). (R 15 (J. Feijo, Dep. at 200)).

16. According to James and Patricia Feijo, DCO was created for the purpose of healing based on the scripture of Daniel Chapter One and other biblical verses including Genesis 1:29, where, according to James and Patricia Feijo, God said he created food for healing. (J. Feijo, Tr. 417-23; Deposition of Patricia Feijo, Jan. 14, 2009 (hereinafter referred to as R 16 (P. Feijo, Dep. at ___)) at 39-40).

17. According to Patricia Feijo, the name Daniel Chapter One comes from the Book of Daniel in the Old Testament of the Bible, in which, Daniel and his men were in captivity and were expected to eat the king's very rich diet of meats and wine, but instead ate and drank only pulse and water; after 10 days, their eyes were said to be brighter and they were said to be stronger than the king's men. (R 16 (P. Feijo, Dep. at 40-41)).

18. According to James and Patricia Feijo, DCO's ministry activities include helping house churches in other countries, holding religious meetings, performing baptisms, delivering babies, performing marriage ceremonies, performing healings, and reaching out to interested persons to inform them about Respondents' perspectives on the integration of spiritual and physical well-being. (R 16 (P. Feijo, Dep. at 204-05); J. Feijo, HOJ Tr. 99, 180-83, 236-37; R 15 (J. Feijo, Dep. at 73); P. Feijo, Tr. 325-26).

19. Respondent James Feijo has provided nutritional counseling to some individuals and has let people in need stay in the house with the Feijos. (P. Feijo, HOJ Tr. 268-71).

20. Respondents have provided support to a junior men's fast-pitch softball team. (P. Feijo, HOJ Tr. 263).

21. In some instances, Respondents have given away, or have provided at a reduced price, DCO products. (R 15 (J. Feijo, Dep. at 209-11); R 16 (P. Feijo, Dep. at 69); J. Feijo, HOJ Tr. 137, 184-88; P. Feijo, HOJ Tr. 263, 268, 274; Mink, HOJ Tr. 293-94; Hicks, HOJ Tr. 306-07).

3. Incorporation of Daniel Chapter One

22. Respondent DCO was previously incorporated as "Daniel Chapter One, Inc.," a Rhode Island for-profit corporation, on October 10, 1990. (CX 50; J. Feijo, HOJ Tr. 101).

23. Respondent DCO's Articles of Incorporation from 1990 state that the purposes for which Daniel Chapter One, Inc. was organized were: "[T]o engage in the sale, retail, wholesale and distribution of health products, including but not limited to health foods and supplements, namely those with special nutritive qualities and values." (CX 50; J. Feijo, HOJ Tr. 101-02).

24. Respondent DCO filed annual reports from 1991 through 1997, during which time the stated character of the business remained substantially similar, namely, "to engage in the

sale, retail, wholesale and distribution of health products, including health foods and supplements." (CX 50; J. Feijo, HOJ Tr. 102-08).

25. Each of these for-profit corporation annual reports of DCO bears the signature of Respondent James Feijo. (J. Feijo, HOJ Tr. 102-08).

26. From 1991 to 1997, DCO's corporate status was repeatedly revoked. (J. Feijo, HOJ Tr. 175-77, 194-97; CX 50).

27. Respondent James Feijo sold the Challenged Products while DCO was registered as a for-profit corporation. (J. Feijo, Tr. 417-18; R 15 (J. Feijo, Dep. at 224)).

28. In 2002, Respondent Daniel Chapter One was organized as a corporation sole under the laws of the State of Washington. (Answer ¶ 1; CX 31; J. Feijo, HOJ Tr. at 84).

29. DCO's Articles of Incorporation as a corporation sole describe its purposes as follows:

> [T]o do whatever will promote the Kingdom Of God, All Righteousness, and the principals [sic] of Liberty and Justice to provide for the comfort, happiness and improvement of an indefinite number of natural men and women, with special forerunner emphases upon the firm practice and lawful operation of the law, providing lawful advice, educating people in the fundamental principles of liberty and the common law, researching, developing and implementing remedies at law

> for any problem while holding accountable those individuals responsible for the breach of, or wrongful interference with contractual obligations, whether written, verbal, or implied; as well as other worthwhile projects for the common good of Daniel Chapter One and its close associates, along with other acts and programs beneficial to Daniel Chapter One at large.

(CX 31).

30. DCO's Articles of Incorporation do not specifically declare that DCO was organized exclusively for charitable or other clearly nonprofit purposes. DCO's Articles of Incorporation do not provide for distribution of its assets upon dissolution solely to other nonprofit entities or prohibit distribution of its earnings to the benefit of any individual or for-profit corporation. (CX 31).

31. DCO is not registered with the Internal Revenue Service as a charity. (R 15 (J. Feijo, Dep. at 45); J. Feijo, HOJ Tr. 209).

32. DCO's advertising and promotional materials (*see infra* Section II D, E) do not specifically refer to DCO as a nonprofit entity. For example, the "About Us" section on the DCO Website, www.danielchapterone.com, describes DCO as a "health food store" or "health food supplement store." (CX 1).

33. DCO uses, but does not own, two buildings in Rhode Island – one is the telephone order center (*see infra* F. 99) and the other is the warehouse. (J. Feijo, HOJ Tr. 110; R 15 (J. Feijo, Dep. 72-73)).

34. Messiah Y'Shua Shalom, a State of Washington corporation sole, owns one of the two buildings that Respondents use in Rhode Island. (R 15 (J. Feijo, Dep. at 72-73); CX 35). The other building is rented from an owner unrelated to Respondents. (R 15 (J. Feijo, Dep. at 174)).

35. Respondent James Feijo is also the overseer for Messiah Y'Shua Shalom. (R 15 (J. Feijo, Dep. at 72-73); CX 35).

36. Respondents founded Accent Radio Network in 2000. (CX 32 at FTC-DCO 2954; J. Feijo, HOJ Tr. 110-12).

B. Respondents' Finances

1. Control by James Feijo

37. Respondent James Feijo is responsible for the development, creation, production, and pricing of the Challenged Products. (CX 39 (Respondents' Answer to Interrogatory No. 2); R 15 (J. Feijo, Dep. at 116); R 16 (P. Feijo, Dep. at 77)).

38. Respondent James Feijo and his wife, Patricia Feijo, have been solely responsible for creating, drafting, and approving the directions for usage of the Challenged Products. (CX 39 (Respondents' Answer to Interrogatory No. 16)).

39. Respondent James Feijo and Patricia Feijo developed the recommended dosages of the Challenged Products. (R 16 (P. Feijo, Dep. at, 166-67, 175, 192); CX 39 (Respondents' Answer to Interrogatory No. 16).

40. Respondent James Feijo is the trustee for all of DCO's assets, including all funds, which are to be held in trust. (CX 39 (Respondents' Answer to Interrogatory Nos. 3, 9); J. Feijo, HOJ Tr. 73).

41. Respondent James Feijo is ultimately in charge of DCO. (J. Feijo, HOJ Tr. 112).

2. Bank accounts

42. Respondent DCO has bank accounts with Citizens Bank, including: Daniel Chapter One Business Partners Checking, Daniel Chapter One Business Partners Money Market Fund, Daniel Chapter One DBA Creation Science Funding, and Daniel Chapter One DBA Radio Leasing International. Revenue earned by Respondent DCO is deposited into the Daniel Chapter One Business Partners Checking account and from there is distributed, at Respondent James Feijo's discretion, to the other DCO bank accounts. (CX 49; J. Feijo, HOJ Tr. 206-08, 227, 230).

43. Records of the Daniel Chapter One Business Partners Checking account show frequent ATM cash withdrawals in the amount of $803, including multiple such withdrawals in the same

month. (CX 49, *see, e.g.*, FTC-DCO 3661, 3666, 3671, 3677, 3683, 3689).

44. The Daniel Chapter One Business Partners Money Market Fund held unused funds that Respondents put aside. (J. Feijo, HOJ Tr. 230).

45. Records from the Daniel Chapter One Business Partners Money Market Fund show that from December 19, 2006 until February 20, 2008, the money market fund had a balance in excess of $1,000,000, and grew to as high as $1,303,283. On February 21, 2008, a debit was posted in the amount of $802,000. (CX 49 at FTC-DCO 3624-97).

46. According to James Feijo, DCO does not keep a ledger of the amounts it pays out. (J. Feijo, HOJ Tr. 166).

47. According to James Feijo, the trustee of DCO's funds, Feijo does not keep track of the money DCO distributes; Feijo is not aware of what bank accounts DCO has; and Feijo has no idea how much DCO pays out on a monthly basis for its credit cards. (J. Feijo, HOJ Tr. 165, 168-69, 227-28).

48. Patricia Feijo is a signatory to DCO's bank accounts and writes checks from the DCO accounts. (R 16 (P. Feijo, Dep. at 54); P. Feijo, HOJ Tr. 276).

49. Jill Feijo, James Feijo's daughter, pays DCO's bills. (J. Feijo, HOJ Tr. 204).

3. Records

50. DCO has a policy of not maintaining records. (J. Feijo, HOJ Tr. 73, 83).

51. Respondent James Feijo did not change DCO's document retention policies after learning that the FTC had brought a proceeding against him and DCO. (J. Feijo, HOJ Tr. 80). DCO did not change its document retention policies after receiving the Court's first and second orders to produce certain documents to Complaint Counsel. (J. Feijo, HOJ Tr. 81-83).

52. Respondent James Feijo had the authority to change DCO's document retention policies after receiving the orders in this proceeding to produce responsive documents to Complaint Counsel. (J. Feijo, HOJ Tr. 83).

53. DCO continued to discard documents, including Marino's purchase order form (*see infra* F. 154-55), even after receiving orders in this proceeding to produce certain documents to Complaint Counsel. (J. Feijo, HOJ Tr. 83).

54. DCO has no records indicating how much of its products it has given away or how much financial support DCO has dedicated to charitable activities. (P. Feijo, HOJ Tr. 274-75).

4. Distribution of funds

55. James and Patricia Feijo live at the Portsmouth, Rhode Island property, owned by Messiah Y'Shua Shalom, as well as in a three-bedroom house owned by DCO, with a pool on country

club land, in Deerfield Beach, Florida. (R 15 (J. Feijo, Dep. at 70-71, 78-79); J. Feijo, HOJ Tr. 160, 204).

56. Respondent DCO owns two cars, a 2003 Cadillac and a 2004 Cadillac. DCO purchased one Cadillac new and the other Cadillac used. (R 15 (J. Feijo, Dep. at 71); J. Feijo, HOJ Tr. 160).

57. Respondent James Feijo uses the two Cadillacs owned by DCO. (R 15 (J. Feijo, Dep. at 96-97); J. Feijo, HOJ Tr. 160).

58. Respondent DCO pays for all of the Feijos' living expenses. (CX 39 (Respondents' Answer to Interrogatory No. 3); J. Feijo, HOJ Tr. 206; P. Feijo, HOJ Tr. 276).

59. Respondents do not maintain any records of how much DCO money is spent on the Feijos' living expenses. (P. Feijo, HOJ Tr. 277).

60. The Feijos do not file tax returns with regard to the money they receive from Respondent DCO. (P. Feijo, HOJ Tr. 278).

61. Respondent DCO pays for pool and gardening services rendered on the "Feijo house" in Florida. (CX 49 at FTC-DCO 3443, 3457).

62. Respondent DCO pays for Patricia Feijo's tennis club membership. (P. Feijo, HOJ Tr. 278).

63. Respondent DCO pays for Respondent James Feijo's membership at the Green Valley Country Club in Rhode Island. (J. Feijo, HOJ Tr. 154-55).

64. Respondent DCO pays for Respondent James Feijo to play golf at the Deer Creek Golf Course located behind the Deerfield Beach, Florida home. (CX 49; J. Feijo, HOJ Tr. 155).

65. Respondent DCO has an American Express Business Gold Card, in the names of Daniel Chapter One and of Patricia Feijo, to which Respondent James Feijo is also a signatory. (CX 48; P. Feijo, HOJ Tr. 276).

66. Respondent James Feijo has frequently used the American Express Business Gold Card to eat at restaurants, play golf, and buy cigars and other retail items. Patricia Feijo also frequently used the card at grocery stores, drug stores, book stores, gas stations, clothing and shoe stores, and home furnishing stores, such as Bed, Bath & Beyond, and Linens & Things. (CX 48; J. Feijo, HOJ Tr. 151-60; P. Feijo, HOJ Tr. 276).

67. Approximately $9,936 was charged for golf expenses on DCO's American Express Business Gold Card during the period from December 2005 through March 2009. (CX 48 at FTC-DCO 2985, 2995, 3003, 3004, 3011, 3039, 3049, 3081, 3082, 3091, 3092, 3103, 3104, 3111, 3113, 3119, 3129, 3171, 3174, 3181, 3182, 3189, 3208B, 3208C, 3208M, 3210, 3237, 3264, 3297).

68. Approximately $14,024 was charged for restaurant expenses on DCO's American Express Business Gold Card during the period from December 2005 through March 2009. (CX 48 at FTC-DCO 2966, 2975, 2985, 2995, 2996, 3003, 3011, 3012, 3019, 3027, 3028, 3039, 3040, 3049,

3057, 3058, 3059, 3067, 3068, 3081, 3091, 3103, 3113, 3129, 3137, 3181, 3182, 3197, 3208A, 3208B, 3208K, 3208M, 3209, 3210, 3217, 3218, 3225, 3235, 3238, 3245, 3251, 3255, 3264, 3265, 3274, 3275, 3284).

69. Approximately $28,582 was charged for automobile expenses on DCO's American Express Business Gold Card during the period from December 2005 through March 2009. (CX 48 at FTC-DCO 2966, 2975, 3003, 3011, 3019, 3027, 3039, 3049, 3050, 3057, 3065, 3068, 3082, 3103, 3105, 3113, 3127, 3129, 3165, 3173, 3181, 3189, 3208B, 3231, 3238, 3245, 3264, 3265, 3271, 3273, 3284).

70. Approximately $1,077 was charged for cigar expenses on DCO's American Express Business Gold Card during the period from December 2005 through March 2009. (CX 48 at FTC-DCO 3113, 3121, 3181, 3197, 3208M, 3245, 3264, 3273).

71. Respondent DCO also has credit cards with Bank of America and Chase Bank. (J. Feijo, HOJ Tr. 161).

72. Approximately $51,087 was electronically transferred from Citizens Bank checking accounts of DCO and related entities to Bank of America during the period from February 2007 through March 2009. (CX 49 at FTC-DCO 3352, 3359, 3363, 3367, 3674, 3680, 3685, 3701, 3706, 3726, 3733, 3741, 3750).

73. Approximately $30,277 was paid by check from DCO's Creation Science Funding account with

Citizens Bank to Bank of America during the period from January 2007 through April 2007. (CX 49 at FTC-DCO 3448, 3456, 3470, 3472, 3498).

74. Approximately $25,837 was paid by check from DCO's Creation Science Funding account with Citizens Bank to Chase Card Services during the period from January 2007 through April 2007. (CX 49 at FTC-DCO 3441, 3464, 3470, 3493, 3497).

75. Respondent James Feijo does not retain receipts for his credit card purchases and credit card payments are automatically debited. (J. Feijo, HOJ Tr. 163-64).

76. Respondent James Feijo does not have his own individual bank account. (J. Feijo, HOJ Tr. 208).

77. Respondent James Feijo pays his daughter Jill Feijo $700 per week for her work at DCO. (J. Feijo, HOJ Tr. 204-05).

78. Although he paid individual income taxes prior to DCO's incorporation as a corporation sole, Respondent James Feijo has since stopped paying individual income taxes. (J. Feijo, HOJ Tr. 86).

79. DCO does not pay any state sales tax based on the sale of DCO products through the DCO Website. (J. Feijo, HOJ Tr. 210).

C. Respondents' Sales in Commerce

1. Respondents' sales of the Challenged Products

80. Respondents' sales of the Challenged Products constitute 20 or 30 percent of the approximately $2 million in annual sales of DCO products for the years 2006, 2007, and 2008. (CX 44; R 15 (J. Feijo, Dep. at 206-07, 212); J. Feijo, HOJ Tr. 109, 223-24, 315).

81. Over a thousand people have purchased the Challenged Products. (R 16 (P. Feijo, Dep. at 57)).

82. Anyone can buy and use the Challenged Products, including people who do not belong to the DCO religious community and people who do not believe in God. (Marino, HOJ Tr. 55; P. Feijo, Tr. 410-11).

83. Respondents' acquisition costs for the products they sell is 30 percent of the price Respondents charge for products such as 7 Herb Formula. (R 15 (J. Feijo, Dep. at 232); F. 127-29, 140-42, 144-46).

84. Respondents sell the Challenged Products through publications, a call center, over the Internet, and through stores and distributors. (F. 86, 89-92, 94, 97, 99, 104, 116-17, 163, 174).

a. DCO's publications

85. James and Patricia Feijo claim to have created a combined spiritual and scientific approach that maintains the balance of bodily systems

which James Feijo named BioMolecular Nutrition. (CX 21).

86. Respondents created a publication entitled "BioGuide: The BioMolecular Nutrition Guide to Natural Health 3" ("BioGuide" or "BioGuide 3"). BioGuide 3 is the third printing and the current version that DCO uses. (CX 21; R 16 (P. Feijo, Dep. at 117); R 15 (J. Feijo, Dep. at 243); J. Feijo, Tr. 452-53; P. Feijo, Tr. 388).

87. According to the BioGuide, "[t]here are two aspects of BioMolecular Nutrition, the spiritual and the physical." (CX 21 at FTC-DCO 0307). "The principles of BioMolecular Nutrition were those missing principles needed to bind together those of the nutritionists and the biochemists." (CX 21 at FTC-DCO 0309).

88. The BioGuide states that "[b]ecause of BioMolecular nutritional products developed . . . [the Feijos have] been able to support other naturopathic disciplines – chiropractic, acupuncture, herbology, and homeopathy – and using the principles of BioMolecular Nutrition has allowed many natural health practitioners to be complete." (CX 21 at FTC-DCO 0308).

89. The BioGuide contains descriptions of DCO products, testimonies from people who have used DCO products and doctors who recommend the products, as well as Biblical passages. (CX 21; R 16 (P. Feijo, Dep. at 117); J. Feijo, Tr. 452-53).

90. The BioGuide prominently displays the toll-free number for DCO's call center and the danielchapterone.com web address. (CX 21).

91. Respondents also created the BioMolecular Nutrition Product Catalog, which lists and describes DCO products and states, "Call Toll FREE 1-800-504-5511 or shop online at www.danielchapterone.com." (CX 17).

92. There is no indication in the BioMolecular Nutrition Product Catalog that the price listed beside the products displayed is for a donation. (R 15 (J. Feijo, Dep. at 158); R 16 (P. Feijo, Dep. at 76-77); J. Feijo, HOJ Tr. 140).

93. There is no mention of a DCO ministry in the BioMolecular Nutrition Product Catalog. (R 15 (J. Feijo, Dep. at 161)).

94. Respondents produced a newsletter, "How to Fight Cancer is Your Choice!!!" (hereinafter "Cancer Newsletter"). In the Cancer Newsletter, Respondents instruct consumers to call their toll-free number to order their products. (CX 23; CX 24).

95. The Cancer Newsletter, a one-time brochure reprinted once with minor updates, provides testimonials from users of DCO products. (J. Feijo, Tr. 452).

96. The Cancer Newsletter is available online on DCO's Website. (CX 13 at FTC-DCO 0013; CX 13A at FTC-DCO 2828A).

97. Respondents produced a publication, "The Most Simple Guide to the Most Difficult Diseases:

The Doctors' How-To Quick Reference Guide" (hereinafter "The Most Simple Guide"). (CX 20).

98. "The Most Simple Guide" can be accessed by anyone, not only doctors, on DCO's Website. (P. Feijo, Tr. 395; J. Feijo, Tr. 453-55).

b. Call center sales

99. Respondent DCO has a toll-free number and a call center for consumers to purchase DCO products. (R 16 (P. Feijo, Dep. at 67); J. Feijo, HOJ Tr. 212; P. Feijo, HOJ Tr. 273-74; J. Feijo, HOJ Tr. 168, 204, 211-12).

100. Respondent James Feijo created, managed, and maintained the toll-free telephone number, designed so that consumers can order DCO products and discuss their physical and spiritual well-being. (CX 39 (Respondents' Answer to Interrogatory No. 33); P. Feijo, Tr. 357-58).

101. Respondent James Feijo's daughter, Jill Feijo, has supervised Respondent DCO's order center for the past nine years and has taken telephone orders. (CX 39 (Respondents' Answer to Interrogatory No. 33); J. Feijo, HOJ Tr. 204).

102. Consumers learn of DCO's toll-free number from the BioGuide, DCO Website, and Respondents' radio program, "Daniel Chapter One HealthWatch." (P. Feijo, HOJ Tr. 273-74; CX 21; CX 29 at FTC-DCO 0451).

c. Internet sales

103. Respondents operate the DCO Website (www.danielchapterone.com). (Answer ¶ 5; R 15 (J.

Feijo, Dep. at 62)). DCO also operates the websites www.dc1pages.com, www.dc1store.com, www.7herbformula.com, and www.gdu2000.com (collectively, the "Websites"). (CX 39 (Respondents' Answer to Interrogatory No. 11); R 15 (J. Feijo, Dep. at 62, 232-33); J. Feijo, Tr. 459).

104. DCO accepts consumers' orders over the Internet through the Websites. (P. Feijo, Tr. 397; Marino, HOJ Tr. 54).

105. DCO's Website contains a tab inviting consumers to shop at DCO's "On-Line Store." (CX 12-14).

106. DCO's Website contains an icon inviting consumers to "Buy Now." (CX 12-14; J. Feijo, HOJ Tr. 144).

107. On their website www.dc1store.com, Respondents state: "For Information on Special offers for *purchasing* multiple bottles of 7-Herb call 1-800-504-5511 between 9-6 EST Mon.-Fri." (CX 17 at FTC-DCO 0084 (emphasis added)).

d. Radio broadcasts

108. The "Daniel Chapter One HealthWatch" radio program is broadcast on the "Accent Radio Network" and is carried by what was characterized as an eclectic group of AM radio stations. (CX 32; R 15 (J. Feijo, Dep. at 235); Harrison, Tr. 309-10).

109. Respondent James Feijo and his wife, Patricia Feijo, co-host the Daniel Chapter One radio program for two hours a day, Monday through

Friday. (CX 39 (Respondents' Answer to Interrogatory No. 5); R 15 (J. Feijo, Dep. at 16-17); Harrison, Tr. 303; P. Feijo, Tr. 324; J. Feijo, Tr. 450-51).

110. James and Patricia Feijo have counseled individuals who have called into the Daniel Chapter One radio program and who have identified themselves as cancer patients about taking the Challenged Products. (R 16 (P. Feijo, Dep. at 92-97); P. Feijo, Tr. 360-64).

111. On their radio show, Respondents provide listeners with the toll-free number that people can call to purchase the Challenged Products. (P. Feijo, HOJ Tr. 272-74).

e. Fees and promotions

112. DCO's shipping and handling fees for its products are $20.95. (R 15 (J. Feijo, Dep. at 152-53)).

113. DCO offers coupons to consumers for their next online store order. (R 15 (J. Feijo, Dep. at 154); Marino, HOJ Tr. 59; J. Feijo, HOJ Tr. 149-50).

114. Respondents run sales promotions from time to time to give people an opportunity to purchase products at a lower rate. (R 15 (J. Feijo, Dep. at 154)). For example, consumers can buy multiple bottles and get a bottle free. (R 15 (J. Feijo, Dep. at 232)).

115. Consumers can join DCO's Bucket-A-Month Club to obtain volume discounts on DCO products. (CX 29 at FTC-DCO 0430; J. Feijo, HOJ Tr. 140-41).

f. Stores and distributors

116. A number of stores sell DCO products, including stores in Georgia and a store in Pennsylvania. (R 16 (P. Feijo, Dep. at 72)).

117. Respondents use distributors in various states for DCO products. (J. Feijo, HOJ Tr. 132-35). Respondents' distributors have included stores such as Nature's Pharmacy in Altoona, Florida; Herbs Shop Unlimited in Adel, Georgia; The Poppyseed in Peculiar, Missouri; Herbal Connection in Lake Park, Georgia; Beehive Natural Foods in Poplar Bluff, Missouri; Discount Nutrition in Monroeville, Pennsylvania; and Organic Pride in Plant City, Florida. (J. Feijo, HOJ Tr. 131-32).

118. Respondents call some distributors of DCO products "silver-line carriers" or "gold-line carriers." (J. Feijo, HOJ Tr. 125). "Gold-line carriers" carry a broader range of products than "silver-line carriers." (J. Feijo, HOJ Tr. 126).

119. Respondents' distributors have also included chiropractic centers. (J. Feijo, HOJ Tr. 134-35).

120. Doctors and stores that carry DCO's product line get the products at prices below their listed prices because they are going to resell the products. (R 16 (P. Feijo, Dep. at 71)).

121. One doctor who is a distributor of DCO products places about a 40 percent markup on the DCO products he sells. (Mink, HOJ Tr. 287-88; J. Feijo, HOJ Tr. 311).

122. Respondents have created a brochure entitled "The Truth Will Set You Free!" for the stores and doctors' offices that carry DCO products. (CX 22; J. Feijo, HOJ Tr. 135). Among the benefits listed in the brochure are financial rewards such as "boost[ed] sales" and "earnings potential." (CX 22; J. Feijo, HOJ Tr. 136-37). The brochure also states that Respondent DCO "is the ONLY nutrition company where the owners personally tell thousands of people to visit your office or store." (CX 22).

123. On their webpage www.dc1store.com, Respondents promote an affiliate program, stating:

> **Welcome to the DC1 Affiliate Program!** Our program is free to join, it's easy to sign-up and requires no technical knowledge. Affiliate programs are common throughout the Internet and offer website owners a means of *profiting* from their websites. Affiliates *generate sales* for commercial websites and in return receive a percentage of the value of those sales. **How Does It Work?** When you join the DC1 Affiliate Program, you will be supplied with a range of banners and textual links that you place within your site. When a user clicks on one of your links to the DC1 Affiliate Program, their activity will be tracked by our affiliate software. You will earn a commission based on your commission type. **Real-Time Statistics and Reporting!** Login 24 hours a day to check your

> sales, traffic, account balance and see how your banners are performing. You can even test conversion performance by creating your own custom links! **Affiliate Program Details.** Pay-Per-Sale: 10% of all sales you deliver. $100.00 USD – Minimum balance required. . . . Payments are made on the 1st of each month, for the previous month."

(CX 29 at FTC-DCO 0461-0462 (emphasis in bold in original; emphasis in italics added)).

124. An entity does not have to be a religious ministry to participate in the DC1 Affiliate Program. (J. Feijo, HOJ Tr. 114).

2. Sales information for each of the Challenged Products

125. There has been only one version of each of the Challenged Products and the information relating to the identity of each ingredient and the amount of each ingredient contained on the labels of the Challenged Products. (CX 39 Respondents' Answer to Interrogatory No. 17).

a. BioShark

126. BioShark is a product that contains, among other ingredients, shark cartilage. (Answer ¶ 6). Each BioShark product label directs users to take two to three capsules three times a day or as directed by a physician or by a BioMolecular

Nutrition health care professional. (Answer ¶ 6; CX 17 at FTC-DCO 0065).

127. Respondents offer one bottle of BioShark for $30.95 (for 100 of the 800 mg capsules) and another bottle of BioShark for $65.95 (for 300 of the 800 mg capsules). (Answer ¶ 6).

128. Respondents pay Universal Nutrition $3.15 per unit for the 100 capsule bottle of BioShark and $8.75 per unit for the 300 capsule bottle of BioShark. (Deposition of Claudia Petra Bauhoffer-Kinney, Jan. 15, 2009 (hereinafter referred to as R 17 (Bauhoffer-Kinney, Dep. at ___) at 44).

129. During 2008, Respondents paid Universal Nutrition approximately $1,437 to manufacture 479 units of the 100 capsule bottle of BioShark and approximately $6,256 to manufacture 782 units of the 300 capsule bottle of BioShark. (R 17 (Bauhoffer-Kinney, Dep. at 44-45)).

130. Universal Nutrition has its own brand of products and is also a private-label manufacturer. (R 17 (Bauhoffer-Kinney, Dep. at 17)).

131. DCO falls under the private-label side of Universal Nutrition. (R 17 (Bauhoffer-Kinney, Dep. at 17)).

132. Universal Nutrition makes approximately thirty-five to forty products for DCO, including BioShark, GDU, and BioMixx. (R 17 (Bauhoffer-Kinney, Dep. at 20-21)).

133. Universal Nutrition started manufacturing BioShark for Respondents approximately eight to ten years ago. (R 17 (Bauhoffer-Kinney, Dep. at 42-43)).

b. 7 Herb Formula

134. 7 Herb Formula is a liquid tea concentrate product that contains, among other ingredients, distilled water, cat's claw, burdock root, Siberian ginseng, sheep sorrel, slippery elm, watercress, and Turkey rhubarb root. The 7 Herb Formula is an essiac formula to which Respondents added cat's claw and Siberian ginseng. (Answer ¶ 8; J. Feijo, HOJ Tr. 146-48; J. Feijo, Tr. 439).

135. Respondents' product label directs users to take one to two ounces of 7 Herb Formula with two to four ounces of hot or cold, filtered or distilled water. The label further directs users to take 7 Herb Formula twice daily or as directed by a BioMolecular Nutrition health care professional. (Answer ¶ 8; CX 17 at FTC-DCO 0064).

136. Respondents offer one thirty-two ounce bottle of 7 Herb Formula for $70.95. (Answer ¶ 8).

137. On their websites www.danielchapterone.com and www.dc1pages.com, Respondents state regarding 7 Herb Formula: "I think it costs too much: Essiac formulas normally retail for $45 to $69 per bottle. If you compare that to the cost of a hospital stay and drug treatment, this is cheap! Daniel Chapter One's 7 Herb Formula

is equally priced with most other brands but with ours you get a great deal more. Remember you are not only getting 32 ounces per bottle, when some of the other brands are only 16 ounces; you are also getting 2 more expensive herbs (Cat's Claw and Siberian Ginseng). We use 3 times the herbs and prepare each individually using a double water filtering process. If that is the case you must at least double the price they are asking to get equal price comparison." (CX 18 at FTC-DCO 0159-60).

138. On the DCO Website, Respondents state: "Daniel Chapter One is the first and only company to add Siberian Ginseng to the formula." (CX 30).

c. GDU

139. GDU is a product that contains, among other ingredients, bromelain, turmeric, quercetin, feverfew, and boron. (Answer ¶ 10). "GDU" stands for "gelatin digesting units." (J. Feijo, Tr. 442). Respondents' GDU product label directs users to take three to six capsules two to four times per day or as directed by a physician or by a BioMolecular Nutrition health care professional. (Answer ¶ 10; CX 17 at FTC-DCO 0068).

140. Respondents offer GDU for $29.95 (for 120 capsules) and $45.95 (for 300 capsules). (Answer ¶ 10).

141. Respondents pay Universal Nutrition $3.28 per unit for the 120 tablet bottle of GDU and $7.07

per unit for the 300 tablet bottle of GDU. (R 17 (Bauhoffer-Kinney, Dep. at 34-35)).

142. During 2008, Respondents paid Universal Nutrition approximately $5,127 to manufacture 1,709 units of the 120 tablet bottle of GDU and approximately $52,661 to manufacture 7,523 units of the 300 tablet bottle of GDU. (R 17 (Bauhoffer-Kinney, Dep. at 34-35)).

d. BioMixx

143. BioMixx is a product that contains, among other ingredients, goldenseal, echinacea, and ginseng. (Answer ¶ 12). Respondents' product label for BioMixx directs users to take five scoops daily. (Answer ¶ 12; CX 18 at FTC-DCO 0127).

144. Respondents offer BioMixx for $40.95 (for 3 pounds of powder) and $22.95 (for one pound of powder). (Answer ¶ 12).

145. Respondents pay Universal Nutrition $11.50 per unit for the three pound bottle of BioMixx. (R 17 (Bauhoffer-Kinney, Dep. at 46)).

146. During 2008, Respondents paid Universal Nutrition approximately $8,778 to manufacture 798 units of the three pound bottle of BioMixx. (R 17 (Bauhoffer-Kinney, Dep. at 46)).

3. Purchase of the Challenged Products by the FTC investigator

147. On January 3, 2008, FTC investigator Michael Marino ("Marino") purchased the Challenged

Products from the DCO Website. (CX 10; Marino, HOJ Tr. 53-55, 62-67).

148. At the time of Marino's purchase, each of the Challenged Products was displayed on the DCO Website with a picture of the product, a short description of the product, and a corresponding price. (Marino, HOJ Tr. 54).

149. Nothing on the DCO Website indicated to Marino that the Challenged Products could be obtained in exchange for a donation, could be purchased at a reduced price, or could be received for free. (Marino, HOJ Tr. 54-55).

150. Nothing on the DCO Website indicated to Marino that a consumer would have to be part of any religious community in order to purchase the Challenged Products. (Marino, HOJ Tr. 55).

151. Prior to making the purchase of the Challenged Products, Marino created an undercover e-mail account to confirm and monitor the progress of the purchase. Marino received four e-mails from DCO relating to the purchase of the Challenged Products. (CX 33; Marino, HOJ Tr. 56-59).

152. One of the e-mails Marino received from DCO, which was sent the day after he purchased the Challenged Products, stated: "Thank you for your purchase on our online store. . . . We appreciate your business with us," and offered a ten percent discount on a subsequent purchase. (CX 33; Marino, HOJ Tr. 59).

153. On or about January 3, 2008, Marino purchased the Challenged Products, and received all four of the Challenged Products thereafter. (CX 33, 34; Marino, HOJ Tr. 55-60).

154. Included in the shipment of the DCO Products ordered by Marino were the following: "BioGuide 3: The BioMolecular Nutrition Guide to Natural Health 3," "BioMolecular Nutrition Product Catalog," a blank purchase-order form, and an invoice form. (CX 34; Marino, HOJ Tr. 55-56, 61).

155. According to the purchase-order form and invoice, the shipment to Marino originated from Daniel Chapter One, 1028 E. Main Road, PO Box 223, Portsmouth, RI 02871, and was sent to an FTC undercover address in a state in the United States other than Rhode Island. (CX 34; Marino, HOJ Tr. 60).

156. The shipment of the Challenged Products did not contain any documents indicating that the purchase was a donation or thanking the purchaser for making a donation to Daniel Chapter One. (CX 34; Marino, HOJ Tr. 60).

157. According to Commission records, the amount charged to the undercover credit card used for the purchase of the Challenged Products was $175.75. The Commission records indicate that this charge was made by "DANIEL CHAPTER ONE." (CX 34; Marino, HOJ Tr. 58, 60).

D. DCO's Advertisements

158. Information about the Challenged Products is disseminated to the public through a variety of media, the Internet, written publications, and a radio show. (F. 161, 163-64, 169-70, 172, 175-77).

159. DCO has spent money to have its websites and written publications created. (J. Feijo, HOJ Tr. 139).

160. DCO has spent money for cable advertising services. (CX 48 at FTC-DCO 3058).

161. The Challenged Products are advertised on the websites www.danielchapterone.com, www.dc1 pages.com, www.dc1store.com, www.7herbformula.com, and www.gdu2000.com. (CX 39 (Respondents' Answer to Interrogatory No. 11); R 15 (J. Feijo, Dep. at 62, 232-33); J. Feijo, Tr. 459).

162. Any consumer can be directed to the DCO Website by entering the term "cancer" in a Google search. (R 15 (J. Feijo, Dep. at 136)).

163. The DCO publication, "The Most Simple Guide," promotes particular DCO products for particular medical conditions, and each alternating page of this publication sets forth the DCO Website and DCO's toll-free number for telephone orders. (CX 20; J. Feijo, Tr. 453-54). This guide is available to the public to order. (CX 23 at FTC-DCO 0404; CX 24 at FTC-DCO 0420). The guide remains available on the DCO Website where anyone can download it. (CX 29 at FTC-DCO 0430; P. Feijo, Tr. 395). There has

never been a charge to obtain the guide. (P. Feijo, Tr. 382-83).

164. DCO also promotes the Challenged Products through its publication BioGuide 3 ("BioGuide"). (CX 21; CX 39 (Respondents' Answer to Interrogatory No. 11); F. 86, 89-90).

165. James Feijo was responsible for putting together the BioGuide. (R 15 (J. Feijo, Dep. at 243)).

166. Patricia Feijo wrote the content of the BioGuide. (R 16 (P. Feijo, Dep. at 20)).

167. The BioGuide frequently and prominently refers readers to the DCO Website and DCO's toll-free ordering number. (*E.g.*, CX 21 at FTC-DCO 0309-11, 0313).

168. The BioGuide is prominently promoted in the Cancer Newsletter. (CX 23 at FTC-DCO 0397; CX 24 at FTC-DCO 0413 (noting the BioGuide's "Updated Products, Prices, Testimonies! . . . Only $9.95.").

169. The BioGuide is available as a download from the DCO Website. (CX 29 at FTC-DCO 0430). There has never been a charge to obtain the BioGuide. (P. Feijo, Tr. 389).

170. DCO promotes the Challenged Products through its publication, the Cancer Newsletter. (CX 23; CX 24).

171. Although there is a price displayed for the Cancer Newsletter, the Cancer Newsletter was given away without charge. (P. Feijo, Tr. 387).

172. The Cancer Newsletter is available on-line through the DCO Website. (CX 13 at FTC-DCO 0013; CX 13A at FTC-DCO 2828A).

173. The Cancer Newsletter was written primarily by Patricia Feijo. (CX 39 (Respondents' Answer to Interrogatory No. 8); P. Feijo, Tr. 395-96).

174. In the Cancer Newsletter, the toll-free order number and the DCO Website address appear on every other page and on the final page. (CX 23 at FTC-DCO 0392, 0394, 0396, 0398, 0400, 0402, 0404, 0405; CX 24 at FTC-DCO 0407, 0409, 0411, 0413, 0415, 0417, 0419, 0421).

175. The Cancer Newsletter promotes obtaining "The Most Simple Guide" and listening to DCO's radio program. (CX 23 at FTC-DCO 0403-05; CX 24 at FTC-DCO 0419-21).

176. Information about the Challenged Products is disseminated through the radio program, "Daniel Chapter One HealthWatch." (CX 39 (Respondents' Answer to Interrogatory No. 11); P. Feijo, Tr. 325; F. 108-09, 111).

177. "The Most Simple Guide," the BioGuide, and the Cancer Newsletter all promote DCO's radio show. (CX 20 at FTC-DCO 2824; CX 21 at FTC-DCO 0379, CX 23 at FTC-DCO 0405; CX 24 at FTC-DCO 0421). The DCO Website has a link to a webpage for "Talk Radio." (CX 12; CX 13, CX 14).

178. James and Patricia Feijo are responsible for the information provided in the BioGuide, the DCO Website, the Cancer Newsletter, the "Most Simple Guide," and the radio program,

"Daniel Chapter One HealthWatch." (R 15 (J. Feijo, Dep. at 62); J. Feijo, Tr. 452-53; P. Feijo, Tr. 380, 395-96; CX 39 (Respondents' Answer to Interrogatory No. 11-12).

E. DCO's Advertising Claims

1. The Challenged Products collectively

a. Website advertising

179. CX 13 is a printout from a webpage from the DCO Website, entitled "Cancer News." This printout is Exhibit B to the Complaint. CX 13A is another depiction of the same product webpage as that depicted in CX 13, but captured so as to view the entire width of the page. (CX 13; CX 13A).

180. The DCO webpage, Cancer News, contains a picture and text advertising 7 Herb Formula. Directly below the 7 Herb Formula advertisement, the webpage states the following regarding the Challenged Products as a group:

> If you suffer from any type of cancer, Daniel Chapter One suggests taking this products [sic]:
>
> 7*Herb Formula™ 2 ounces in juice or water (minimum intake) 2 times daily
> Bio*Shark™ . . .
> BioMixx™ . . .
> GDU Caps™ . . .
>
> **The above information is taken from The Most Simple Guide to the most difficult diseases, the**

> **doctors' how-to quick reference guide.**
>
> For more information call Jim and Trish during the Radio Show.

Immediately following this text is a prominent picture of bottles of BioMixx, 7 Herb Formula, Bio*Shark, and GDU, and adjacent to that, is a statement in bold: **"Daniel Chapter One's Cancer solutions."** Under the picture, the text states:

> **To Buy the products click here**
>
> **How to fight cancer is your choice!**

(CX 13 at FTC-DCO 0013-14; CX 13A) (emphasis in original).

181. Immediately beneath "How to fight cancer is your choice!" is a quote from a book entitled "Back to Eden," which includes the book author's statement that his "cure for cancer" includes herbs. (CX 13 at FTC-DCO 0014; CX 13A at FTC-DCO 2828B).

182. The "Back to Eden" quote referred to in F.181 is followed by a series of testimonials in bold headlines including: "**Lump is gone without dangerous surgery!,**" "**7 Herb Formula battles cancer,**" "**7 Herb eliminates pre-cancerous growth,**" "**Ancient cancer remedy is improved upon,**" "**Doctors gave up on Michigan man,**" "**Pre-Cancerous Growths & Acid and Heartburn,**" and

"Breast Mass." (CX 13 at FTC-DCO 0014-24) (emphasis in original).

183. The testimonials on the Cancer News webpage claim that the Challenged Products, individually or in combination with each other and/or other DCO products, are effective in the prevention, treatment, or cure of cancer. (CX 13; CX 13A; F. 184-85).

184. The Cancer News webpage includes the following testimonial, accompanied by a picture of a smiling woman:

> **7 Herb Formula battles cancer**
>
> *Tracey was given no hope!*
>
> The doctors had pretty much given up on Tracey. She had leukemia and tumors on the brain, behind the heart and on her liver.
>
> . . .
>
> I had contracted leukemia and had three inoperable tumors. When I decided not to do chemotherapy or radiation, my father sent me Bio*Mixx and 7 Herb Formula. Each day as I took it and got it into my system more and more, the better I felt. Then I added Garlic Pur, Siberian Ginseng, and Bio*Shark. I am now in complete remission. The cancer cell count has dropped, the doctors tell me. I had a tumor just above the brain stem in my brain that has completely

> disappeared. The tumor on my liver is shrinking and the tumor behind my heart has shrunk over 50%. . . .

(CX 13 at FTC-DCO 0016) (emphasis in original).

185. Another testimonial on the Cancer News webpage states:

> **Pre-Cancerous Growths & Acid and Heartburn**
>
> And the most amazing thing was when I had my upper G.I. in September, and the X-ray showed nothing there. . . . [a]fter using 7 Herb and other DC1 products for precancerous growths and for acid & heartburn.

(CX 13 at FTC-DCO 0023) (emphasis in original).

186. The testimonials referred to in F. 184 and 185, as well as other testimonials, are hyperlinked to Cancer News webpage, below the bold-type message: "**Page shortcuts to testimonials about cancer.**" (CX 13 at FTC-DCO 0013) (emphasis in original).

187. At the side of the Cancer News webpage is the bold-type message: **"Listen to our audio testimonials about cancer,"** with bulleted headlines, including "Fred – Breast cancer," "Marie – Dad's throat tumor cured – 7 Herb and more," "Nancy – Cured Breast Cancer in 3 months – 7 Herb and GDU," "Robert – Prostate cured from DC1 products," and "Sharon –

Mom's breast tumor Healed." (CX 13 (emphasis in original); CX 13A).

188. On the side of the Cancer News webpage, there is a link to the Cancer Newsletter. (CX 13; CX 13A).

189. The overall net impression from the www.danielchapterone.com website advertising described in F. 179-88 is that the Challenged Products, individually and/or collectively, prevent, treat, or cure cancer. Viewing the Cancer News webpage as a whole, and the interaction of the words, pictures, and testimonials, the claim that the Challenged Products prevent, treat, or cure cancer is so strongly implied as to be virtually express.

190. The Challenged Products are promoted as a group on the website www.dc1pages.com, where the following text appears:

> **Supporting Products**
>
> To enhance 7 Herb Formula's healing qualities Daniel Chapter One advises to get familiar with the supporting products below. . . .

Immediately below the text is a photograph of bottles of each of the Challenged Products. Adjacent to the picture, in bold print, the following text appears:

> **CANCER**
> **TREATMENT:**
>
> **7 Herb Formula**
> **Bio*Shark**

BioMixx
GDU Caps

also

Ezekiel Oil
topically

(CX 18 at FTC-DCO 0190) (emphasis in original).

191. The overall net impression from the www.dc1pages.com content described in F. 190 is that the Challenged Products, individually and/or collectively, are effective in the treatment of cancer.

b. "The Most Simple Guide to the Most Difficult Diseases"

192. The Challenged Products are promoted collectively for cancer in the DCO publication "The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide." (CX 20). The advertisements in this publication are organized by disease types. (CX 20 at FTC-DCO 2724). On the page for cancer, the following appears:

CANCER
All types of Cancer

7*Herb Formula™
2 ounces in juice or water
(minimum intake)
2 times daily

Bio*Shark™**(for tumors only)**
2-4 capsules
3 times daily with meals

BioMixx™ (Boosts immune system)
4-5 scoops in soy milk
2 times daily

GDU Caps™
3-6 capsules
3 times daily; ½ hr.
BEFORE meals

Next to each product name is a "sun" symbol. The page states: "This sun [symbol] placed before a product indicates the most essential products for the above condition." The only "condition" referred to on that page is cancer. (CX 20 at FTC-DCO 2739) (emphasis in original).

193. The overall net impression from the "cancer" page in the "The Most Simple Guide" described in F. 192 is that the Challenged Products, individually and/or collectively, treat or cure cancer. Viewing the Guide as a whole, and the interaction of the words, pictures, and testimonials, the claim that the Challenged Products prevent, treat, or cure cancer is so strongly implied as to be virtually express

c. Cancer Newsletter

194. The 2002 edition of the DCO Cancer Newsletter is entitled "How to fight cancer is your choice!!!" (CX 23). A two-page excerpt from this newsletter constitutes Exhibit D to the

Complaint. (CX 15). There is also a 2004 version of the Cancer Newsletter. (CX 24). Both the 2002 and the 2004 editions are referred to collectively herein as the "Cancer Newsletter." (CX 23; CX 24).

195. The Cancer Newsletter is "strictly all about the products for cancer" (R 15 (J. Feijo, Dep. at 143)). The Cancer Newsletter contains descriptions of various DCO products that "a person can choose to use to help them fight cancer." (P. Feijo, Tr. 399). These products include BioShark, GDU, BioMixx, and 7 Herb Formula. (P. Feijo, Tr. 402-04).

196. The Cancer Newsletter opens with a quote from a book entitled "Back to Eden," which also appears at the Cancer News webpage of the DCO Website and includes the book author's statement that his "cure for cancer" includes herbs. (F. 181; CX 23 at FTC-DCO 0391; CX 24 at FTC-DCO 0407).

197. The Cancer Newsletter includes descriptions of eight DCO products, four of which are the Challenged Products, and one of which, Siberian ginseng, is an ingredient of one of the Challenged Products, 7 Herb Formula. Interspersed with the product descriptions are testimonials, including testimonials asserting the successful use of one or more of the Challenged Products, and/or other DCO products, for cancer. Other than product descriptions, this publication consists almost entirely of testimonials asserting the successful use of DCO products, including

the Challenged Products, for cancer. (CX 23; CX 24).

198. Many of the testimonials in the Cancer Newsletter are the same as those appearing on the Cancer News webpage of www.danielchapterone.com, including, "Lump Is Gone Without Dangerous Surgery!," "7 Herb Formula Battles Cancer," "7 Herb Eliminates Pre-Cancerous Growth," "Ancient Cancer Remedy Is Improved Upon," "Doctors Gave Up On Michigan Man," and "Pre-Cancerous Growths & Acid and Heartburn." (CX 24 at FTC-DCO 0407; F. 182-85; *see also* CX 17 at FTC-DCO 0100-119 (testimonials).

199. The testimonials in the Cancer Newsletter include such statements as:

- "I started taking the 7 Herb and that tumor was shrinking . . . there has been massive tumor shrinkage." ("Doctors gave up on Michigan man," CX 23 at FTC-DCO 0397; CX 24 at FTC-DCO 0413);

- "Tricia convinced [them] that [the] best hope was to take natural remedies rather than go under the knife. . . . The growth is gone. . . ." ("Cancer Success a Lie!," CX 23 at FTC-DCO 0399; CX 24 at FTC-DCO 0415);

- "With stage 4 cancer and given only 6 months to live, Joe's dad was not doing well . . . . With 4 ounces of 7*Herb Formula per day, in just 2 days . . . the family watched dad's color come back. . . . GDU to

the rescue! . . . PSA 3.3, no pain, alive. . . ." ("Not too late!," CX 23 at FTC-DCO 0401; CX 24 at FTC-DCO 0417).

200. The Cancer Newsletter includes testimonials such as: "Texas businessman has true friends for life," which describes a bladder cancer sufferer who receives a package from friends that "included 7 Herb Formula, . . . BioShark and Bio*Mixx," (CX 23 at FTC-DCO 0400; CX 24 at FTC-DCO 0416); and "Tumor Free!," which describes a brain cancer sufferer who takes "7 HERB, BIO MIXX, BIO SHARK, and GDU Caps," and states, "the tumors were completely gone." (CX 23 at FTC-DCO 0404; CX 24 at FTC-DCO 0420) (emphasis in original).

201. At the bottom of one page in the Cancer Newsletter which includes a description of BioMixx and a testimonial to 7 Herb Formula, BioShark and BioMixx, is the statement, "Visit www.danielchapterone.com TODAY for access to your health questions!" (CX 23 at FTC-DCO 0400; CX 24 at FTC-DCO 0416).

202. The overall net impression from the Cancer Newsletter is that the Challenged Products, individually and/or in combination with one or more of the other Challenged Products, prevent, treat, or cure cancer. (F. 194-201; *see also* F. 182-85, 242 (testimonials)).

d. BioGuide

203. Another DCO publication is entitled "BioGuide: The BioMolecular Nutrition Guide to Natural

Health 3" ("BioGuide"). Interspersed with the product descriptions in the BioGuide are testimonials, including testimonials asserting the successful use of one or more of the Challenged Products and/or other DCO products, for cancer. Other than product descriptions, this publication consists almost entirely of testimonials about DCO products. (CX 21).

204. In the BioGuide, on the page immediately following an advertisement for 7 Herb Formula, there is a picture of a smiling woman and the heading, in large, colored, and bold type, **"Cancer Brain Tumor."** Next to that entry is the colored, italicized text:

> ***The doctors had pretty much given up on Tracey. She had leukemia and tumors on the brain, behind the heart and on her liver.***

The testimonial continues in pertinent part:

> I had contracted leukemia and had three inoperable tumors. When I decided not to do chemotherapy or radiation, my father sent me *BIOMIXX* and 7 *HERB FORMULA*. Each day as I took it and got it into my system more and more, the better I felt. Then I added Garlic, Siberian Ginseng, and Bio*Shark. I am now in complete remission. The cancer cell count has dropped, the doctors tell me. I had a tumor just above the brain stem in my brain that has completely disappeared. The tumor on my liver is

> shrinking and the tumor behind my heart has shrunk over 50%. . . .

(CX 21 at FTC-DCO 0353 (emphasis in original); *see also* F. 184, 198 (same testimonial appears on DCO Website and in Cancer Newsletter)).

205. In the BioGuide, next to the testimonial entitled "Cancer Brain Tumor," is a testimonial with the heading, in large, colored, and bold type, **"Lowered PSA,"** which states in part, "My GOOD NEWS is that my PSA went from 6.9 to 6.0 after I finished using my first four bottles of 7 Herb formula, in combination with your Bio C 1000, GDU and other minerals and vitamins. I believe it was your products that did the trick. . . ." (CX 21 at FTC-DCO 0353) (emphasis in original).

206. The BioGuide contains a testimonial with a heading, in large, colored, and bold type, **"Prostate Cancer,"** adjacent to a picture of a smiling man, which states in pertinent part: "I had beam radiation for prostate cancer. I also took 7 Herb Formula, 6 ounces a day, and BioMixx; I never had a bad day, never felt sick. When my PSA went from 7.6 to 0.5 in the month after I finished radiation, my doctor was surprised. Several months later, it was down to 0.16! 7 Herb Formula is extremely well done – fantastic. I still take 2 ounces of 7 Herb Formula every morning; I plan to stay on that forever! I figure 6 ounces (2 morning, 2 afternoon, 2 evening) did such a good job fighting cancer,

2 ounces is a good prophylaxis!" (CX 21 at FTC-DCO 0330) (emphasis in original).

207. The BioGuide contains a testimonial with a heading, in large, colored, and bold type, **"Renal Cell Cancer,"** next to a picture of a smiling man. The text states in pertinent part:

> I had Renal Cell Cancer in my left kidney, with a tumor attached that was slightly larger than a baseball. I went on 7 Herb Formula and GDU. . . . They had found 3 spots in my lungs, although very small, that are being watched. I continue to drink the 7-Herb, and take Bio-Shark, and GDU. I drink END024 everyday because of the spots in my lungs and ribs. To date, my oncologist is amazed that no further activity has occurred. . . .

Then immediately underneath, the following excerpt is repeated in large, bold, green type:

> ***To date, my oncologist is amazed that no further activity has occurred.***

(CX 21 at FTC-DCO 0317) (emphasis in original).

208. The BioGuide contains a testimonial with a heading in large, colored, and bold type, **"Skin Cancer,"** next to a picture of a smiling couple. The text states in pertinent part that natural products "seemed to stabilize the cancer in that it quit spreading and getting larger but none of it decreased in size. After switching to DC1

products – 7-Herb Formula, BioShark, GDU, Garlic Pur, Siberian Ginseng, Ezekiel Oil and BioMixx – it cleared up quickly." Below this text is a statement in large, bold, colored type:

> ***I had a thorough medical exam three weeks ago and was told I was completely clear of all types of cancer. The doctor didn't know how I got rid of it.***

(CX 21 at FTC-DCO 0357) (emphasis in original).

209. In the BioGuide, next to a large, bold print caption, **"DOCTORS,"** Dr. Jonas and Marla Marry are quoted as stating: "My son was diagnosed with a tumor on his left temple. The tumor was extremely aggressive. . . . [A] friend suggested we speak to Jim and Trish. They suggested 7-Herb, BioShark and GDU, which we bought and started him on. . . . [I]n the time it took us to find a specialist who eventually told us he could not help either, the tumor had already begun to shrink. . . . Four months later the whole family is using the products, as well as my patients, and you would never know my son had a tumor." Next to the testimony are photographs of a happy-looking man and small children. (CX 21 at FTC-DCO 0313).

210. In the BioGuide, next to a large, bold print caption, **"NUTRITION CENTERS,"** Don and Janice Feagin, described as proprietors of a Daniel Chapter One center called the "Herbal Gallery," are quoted as stating: "One lady, who had a history of cancer, used the 7 Herb

Formula, GDU & BioShark and was blessed to get rid of a large breast tumor." Next to these statements is a photograph of a smiling couple. (CX 21 at FTC-DCO 0315).

211. The overall net impression from the portions of BioGuide relating to the Challenged Products, described in F. 203-10, is that the Challenged Products, individually and/or in combination with one or more other Challenged Products, prevent, treat, or cure cancer.

e. The radio show

212. James and Patricia Feijo are not doctors. (R 16 (P. Feijo, Dep. at 114); P. Feijo, Tr. 404; J. Feijo, Tr. 416).

213. James and Patricia Feijo have given treatment advice to cancer patients who have called in to the radio program. (R 16 (P. Feijo, Dep. at 96-97); J. Feijo, HOJ Tr. 221-22; P. Feijo, Tr. 360-64). This treatment advice has involved advising individuals to obtain and take the Challenged Products. (F. 214, 216-17).

214. During the July 8, 2008 DCO HealthWatch radio program, James Feijo stated the following: "Here's a testimony from Pastor Wayne Hamm, Henderson, Nevada. He had the Gulf War illness. He was told that he needed surgery and radiation treatment for his cancer, that he developed skin cancer because of the Gulf War, he was exposed out there. He didn't take it. He decided to use Daniel Chapter One 7 Herb Formula, internally and topically. He

also used Ezekiel Oil topically, BioShark and GDU. [His] skin cleared up after a few months in the late 1980s [sic], early '99, [he] was told there was no trace of cancer. The FDA does not want us to let you know about this." (CX 5 at FTC-DCO 0603).

215. During the July 8, 2008 DCO HealthWatch radio program, James Feijo stated that "the FTC, the FDA, the Canadian Government don't like the fact that we've told people about what to do about natural methods of health and healing, especially cancer." (CX 5 at FTC-DCO 0506).

216. During the July 14, 2008 DCO HealthWatch radio program, Patricia Feijo stated the following: "And while the FTC does not want us saying that anything natural can be used to treat cancer and that nothing certainly can cure cancer, we know that the truth is different than what they want us to say. The truth is God has given us herbs in His creation and nutrients that can heal cancer, even cure cancer." (CX 8 at FTC-DCO 0612).

217. During the July 14, 2008 DCO HealthWatch radio program, Patricia Feijo advised an individual whose father was diagnosed with colon cancer that she should get her father "on . . . GDU, BioShark and 7 Herb Formula. And if you can get him to, you know, go right now to the website, How To Fight Cancer Is Your Choice, or you can get him a hard copy from our order center, while we have them. It's what the FTC wants to shut us down over and they

certainly want us to, you know, crash the website and they want to, you know, burn our material. They don't want us circulating How To Fight Cancer Is Your Choice." (CX 8 at FTC-DCO 0693-0694).

f. Summary

218. The DCO publications and their content referred to in F. 161, 163, 164, 168, 170, 179-88, 190, 192, 194-201, 203-10 are for the purpose of inducing, are likely to induce, and did induce, directly or indirectly, the purchase of the Challenged Products in interstate commerce. (F. 8-9, 80-81, 106, 159-78, 180, 221, 266).

219. The DCO advertising for the Challenged Products collectively, referred to in F. 179-88, 190, 192, 194-201, and 203-10, makes claims that relate to consumer health. (F. 189, 191, 193, 202, 211).

2. BioShark

a. DCO Website

220. CX 12, a printout of the webpage for BioShark on the DCO Website, is Exhibit A to the Complaint. CX 12A is another depiction of the same product webpage as CX 12, but captured so as to show the entire width of the page. (CX 12; CX 12A).

221. The webpage content begins with a heading in bold type, **"Immune Boosters."** Underneath that heading is a picture of bottles of BioShark,

and under that a phrase in small print, "shark cartilage Supplemental Facts." Immediately appearing under this small phrase is the following:

Bio*Shark: Tumors & Cysts

Pure skeletal tissue of sharks which provides a protein that inhibits angiogenesis – the formation of new blood vessels. This can stop tumor growth, and halt the progression of eye diseases such as diabetic retinopathy and macular degeneration. Should not be used by pregnant women, or immediately after heart surgery. Shark cartilage may also reduce the pain, inflammation, and joint stiffness of arthritis, alleviate inflammatory bowel disease, and reverse psoriasis. Shark cartilage is an excellent source of Calcium, Phosphorus, amino acids, and a family of carbohydrates called mucopholysaccharides (sulfated Oligosaccharides and Chondriotin Sulfates A and C).

In summary, Bio*Shark works to reduce inflammation and swelling, affects the formation of new blood vessels and provides essential nutrients for healing.

Warning: If you are pregnant, nursing a baby, recovering from recent surgery, or have a heart or circulatory condition, consult a health professional before using shark cartilage!

Adjacent to that text is a shopping cart icon with the instruction, **"BUY NOW!"** Immediately below that is the message: "Read our clients [sic] testimonials on BioShark & Tumors," and a link to a bulleted title "Cancerous Tumor." At the bottom of the webpage is a link to "Stop Tumor Growth & Cysts Top." (CX 12; CX 12A) (emphasis in original).

222. The words used to describe BioShark on the DCO Website product webpage, as set forth in F. 221 – "Pure skeletal tissue of sharks which provides a protein that inhibits angiogenesis – the formation of new blood vessels. This can stop tumor growth" – strongly imply that BioShark inhibits tumors.

223. An earlier version of the DCO Website stated "Bio*Shark Shark Cartilage Stops tumor growth in its tracks." (CX 18 at FTC-DCO 2032).

224. The overall net impression from the BioShark product webpage on the DCO Website is that BioShark inhibits the growth of tumors, including cancerous tumors. (F. 220-22).

225. The Cancer News webpage on the DCO Website includes the following statements under the heading, in bold type, **Bio*Shark ™**:

> In 1983, two researchers at the Massachusetts Institute of Technology published a study showing that shark cartilage contains a substance that significantly inhibits the development of blood vessels that nourish solid

> tumors, thereby limiting tumor growth. This effect is called anti-angiogenesis.
>
> Scientists recognize the benefits of starving a tumor to limit its growth. They have been looking for a drug to patent that can do the same thing as shark cartilage. They say the answer to curing cancer lies in preventing angiogenesis – the formation of blood vessels which feed the tumor. These scientists are trying to replicate what God has already presented to us so that they can claim rights to it, patent it and make a lot of money. But man can never lab synthesize a product and make it exactly the same – and all drugs have harmful side effects.
>
> Researchers have also demonstrated that shark cartilage can reduce the inflammation and pain associated with arthritis, alleviate psoriasis and have a positive effect on other degenerative diseases.

(CX 13 at FTC-DCO 0023) (emphasis in original).

226. The DCO webpage, "Cancer News," which makes representations regarding the Challenged Products as a group (F. 180-88) states: "If you suffer from any type of cancer, Daniel Chapter One suggests" taking several DCO products, including BioShark. Following the text is a prominent picture of a bottle of BioShark, adjacent to which, is a statement in

bold type, **"Daniel Chapter One's Cancer solutions."** Under the picture, the text states:

> **To Buy the products click here**
>
> **How to fight cancer is your choice!**

(CX 13 at FTC-DCO 0013-0014; CX 13A) (emphasis in original).

227. The overall net impression from the information on the Cancer News webpage on the DCO Website set forth in F. 225-26 is that BioShark is effective in the treatment or cure of cancer, including cancerous tumors. *See also* F. 189.

b. BioGuide

228. The BioGuide includes the following product description for BioShark:

> Pure skeletal tissue of sharks which provides a protein that inhibits angiogenesis – the formation of new blood vessels. This can stop tumor growth, and halt the progression of eye diseases such as diabetic retinopathy and macular degeneration. Should not be used by pregnant women, or immediately after heart surgery. Shark cartilage may also reduce the pain, inflammation, and joint stiffness of arthritis, alleviate inflammatory bowel disease, and reverse psoriasis. Shark cartilage is an excellent source of Calcium, Phosphorus, amino acids, and a family of carbohydrates called

mucopholysaccharides (sulfated Oligosaccharides and Chondriotin Sulfates A and C).

*In summary, Bio*Shark works to reduce inflammation and swelling, affects the formation of new blood vessels and provides essential nutrients for healing.*

Warning: If you are pregnant, nursing a baby, recovering from recent surgery, or have a heart or circulatory condition, consult a health professional before using this product.

(CX 21 at FTC-DCO 0322) (emphasis in original).

229. The words used to describe BioShark in the BioGuide, as set forth in F. 228 – "Pure skeletal tissue of sharks which provides a protein that inhibits angiogenesis – the formation of new blood vessels. This can stop tumor growth . . . " – strongly imply that BioShark inhibits tumors.

230. The overall net impression of the portions of the BioGuide regarding BioShark is that BioShark inhibits tumor growth, and is effective in the prevention, treatment, or cure of cancer. (F. 204, 207-11. 228-29).

c. Cancer Newsletter

231. The Cancer Newsletter includes a page on BioShark. Adjacent to testimonials with headlines in large, bold, and highlighted type, **"Doctors gave up on Michigan Man," and**

"Pre-Cancerous Growths & Acid and Heartburn," the following product information about BioShark appears:

> In 1983, two researchers at the Massachusetts Institute of Technology published a study showing that shark cartilage contains a substance that significantly inhibits the development of blood vessels that nourish solid tumors, thereby limiting tumor growth. This effect is called anti-angiogenesis.
>
> Scientists recognize the benefits of starving a tumor to limit its growth. They have been looking for a drug to patent that can do the same thing as shark cartilage. They say the answer to curing cancer lies in preventing angiogenesis – the formation of blood vessels which feed the tumor. These scientists are trying to replicate what God has already presented to us so that they can claim rights to it, patent it and make a lot of money. But man can never lab synthesize a product and make it exactly the same – and all drugs have harmful side effects.
>
> Researchers have also demonstrated that shark cartilage can reduce the inflammation and pain associated with arthritis, alleviate psoriasis and have a positive effect on other degenerative diseases.

(CX 23 at FTC-DCO 0397; CX 24 at FTC-DCO 0413) (emphasis in original).

232. The overall net impression from the Cancer Newsletter is that BioShark is effective in the treatment or cure of cancer. (F. 195, 197, 200-02, 231).

d. BioMolecular Nutrition Product Catalog

233. The BioMolecular Nutrition Product Catalog states the following regarding BioShark: "Shark Cartilage protein inhibits angiogenesis, stops tumor growth, and halts eye diseases. Reduces pain, inflammation, joint stiffness of arthritis, inflammatory bowel disease, and reverses psoriasis. Affects the formation of new blood vessels." (CX 17 at FTC-DCO 0061).

234. The phrase, "stops tumor growth," in the BioMolecular Nutrition Product Catalog description for BioShark, and set forth in F. 233, expressly claims that BioShark inhibits tumors. (F. 233).

235. The overall net impression from the portion of the BioMolecular Nutrition Product Catalog relating to BioShark, described in F. 233, is that BioShark inhibits tumor growth.

236. The DCO advertising regarding BioShark referred to in F. 221, 225-26, 228, 231, and 233 makes claims that relate to consumer health. (F. 222, 224, 227, 229-30, 232, 234-35).

3. 7 Herb Formula

a. DCO Website

237. The 7 Herb Formula webpage on the DCO Website shows a heading of "Herbs." Underneath that heading, there is a picture of 7 Herb Formula bottles and a close-up of the front of the label. Under the picture is the small print phrase "Supplemental Facts" and a product description, which includes the following:

> **7 Herb Formula: Detoxify, Acid Reflux & Cancer Help**
>
> 7 Herb Formula with Cat's Claw & Siberian Ginseng: Herbs to purify the blood and promote cell repair. The ingredients in this tea concentrate work to clear skin, cleanse the liver, decrease cell mutation, and fight pathogenic bacteria and tumor formation. Also helps regulate blood sugar, heal ulcers, and stop indigestion and heartburn.

(CX 13 at FTC-DCO 0025; CX 13A at FTC-DCO 2840A) (emphasis in original).

238. The DCO product 7 Herb Formula is featured first on the webpage for Cancer News on the DCO Website. The webpage includes a large picture of bottles of 7 Herb Formula and the following statements:

> **7 Herb Formula**
>
> - purifies the blood
> - promotes cell repair

- **fights tumor formation**
- fights pathogenic bacteria

to learn more click here
to buy click here

(CX 13 at FTC-DCO 0013; CX 13A at FTC-DCO 2828A) (emphasis in original).

239. Statements in the product description for 7 Herb Formula on the DCO Website Cancer News webpage that 7 Herb Formula "fights tumor formation" and "decrease[s] cell mutation," as set forth in F. 237-38, clearly imply that 7 Herb Formula inhibits tumors and treats cancer.

240. The DCO webpage, "Cancer News," which makes representations regarding the Challenged Products as a group (F. 180-88) states: "If you suffer from any type of cancer, Daniel Chapter One suggests taking" several DCO products, including 7 Herb Formula ™. Following the text is a prominent picture of a bottle of 7 Herb Formula, adjacent to which is the statement in bold type, "**Daniel Chapter One's Cancer solutions**." Under the picture, the text states:

To Buy the products click here

How to fight cancer is your choice!

(CX 13 at FTC-DCO 0013-14; CX 13A) (emphasis in original).

241. Adjacent to the 7 Herb Formula picture and text on the Cancer News webpage on the DCO

Website are links to the Cancer Newsletter and to "**Page shortcuts to testimonials about cancer**," with titles such as "7 Herb Formula battles cancer" and "7 Herb eliminates pre-cancerous growth." (CX 13 at FTC-DCO 0013; CX 13A at FTC-DCO 2828A) (emphasis in original).

242. Many of the testimonials on the Cancer News webpage are devoted to 7 Herb Formula. For example, a testimonial with the headline "**7 Herb eliminates pre-cancerous growth**" states in part, "I had a pre-cancerous 'wart' on the back of my leg and drinking 7 Herb Formula made it go away." (CX 13 at FTC-DCO 0017) (emphasis in original). The testimonial section also includes a passage entitled "**Ancient cancer remedy is improved upon**," which states in part: "In addition to his sports nutrition line, Jim has developed a line of health supplements and natural remedies. One of the products Jim Feijo is especially proud of is his 7 Herb Formula. . . . Jim improved upon the ancient Ojibway Indian Tribe remedy known as Essiac. . . . As a result of his research, Jim found that by adding Siberian Ginseng and Cat's Claw to the Essiac formula, he could attain remarkable healing results. . . . 'We feel blessed that God has revealed this formula to us and that we have been able to provide those in need of help an alternative to chemotherapy and radiation,' Jim Feijo said." (CX 13 at FTC-DCO 0019-20 (emphasis in original); *see also* F. 184, 185, 187 (7 Herb Formula testimonials)).

243. A testimonial on the Cancer News webpage with the headline "**Doctors gave up on Michigan man**" tells the story of a caller to the Daniel Chapter One HealthWatch radio program who reportedly suffered from cancer. It describes how the man's brother-in-law heard "Jim and Tricia Feijo talk about the success of 7 Herb Formula in helping people with cancer" on the radio show. Thereafter, according to the testimonial, the man took 7 Herb Formula and experienced "massive tumor shrinkage." (CX 13 at FTC-DCO 0022-23) (emphasis in original).

244. On the DCO Website, in the question and answer section regarding 7 Herb Formula, the response to the statement, "I want the ORIGINAL ESSIAC formula, not some knock off brand," includes the statement: "With Jim Feijo's addition to the [7 Herb] formula, we now have the most effective and potent formula available in the battle against tumors." (CX 30 at FTC-DCO 0493) (emphasis in original).

245. The overall net impression from the DCO Website advertising for 7 Herb Formula is that 7 Herb Formula inhibits tumors and is effective in the prevention, treatment, or cure of cancer. (F. 180, 182, 184-85, 187, 189, 237-38, 240-44).

b. dc1pages.com website

246. On the website www.dc1pages.com, in the question and answer section regarding 7 Herb Formula, the response to the statement, "I want

the ORIGINAL ESSIAC formula, not some knock off brand," includes the statement: "With Jim Feijo's addition to the [7 Herb] formula, we now have the most effective and potent formula available in the battle against tumors." (CX 18 at FTC-DCO 0140-42).

247. On the website www.dc1pages.com, in the question and answer section regarding 7 Herb Formula, the response to the statement, "I use Brand X," includes the statement: "The 7 Herb Formula has been used by patients involved in clinical studies in cancer clinics and sold in doctor's offices around the country." (CX 18 at FTC-DCO 0157).

248. The overall net impression from the www.dc1pages.com content relating to 7 Herb Formula is that 7 Herb Formula inhibits tumors and is effective in treatment of cancer. (F. 190-91, 246-47).

c. BioGuide

249. Three pages in the BioGuide are specifically devoted to promoting 7 Herb Formula. (CX 21 at FTC-DCO 0352-54). Two of those pages contain the following description: "7 Herb Formula with Cat's Claw & Siberian Ginseng: Herbs to purify the blood and promote cell repair. The ingredients in this tea concentrate work to clear skin, cleanse the liver, decrease cell mutation, and fight pathogenic bacteria and tumor formation. Also helps regulate blood sugar, heal ulcers, and stop indigestion and heartburn." (CX 21 at FTC-DCO 0352, 0354). In between

these two pages is a page devoted to two testimonials, "**Cancer Brain Tumor**" and "**Lowered PSA**." (CX 21 at FTC-DCO 0353).

250. The overall net impression from the portions of the BioGuide relating to 7 Herb Formula is that 7 Herb Formula inhibits tumors and is effective in the prevention, treatment, or cure of cancer. (F. 204-11, 249).

d. Cancer Newsletter

251. The Cancer Newsletter includes a page specifically devoted to advertising 7 Herb Formula. That page prominently features the 7 Herb Formula name and logo. The text includes the statements: "How does it work? Daniel Chapter One's 7 Herb Formula has been created to purify the blood and to promote cell repair. It fights pathogenic bacteria and tumor formation. The ingredients . . . cleanse the liver and decrease cell mutation." (CX 23 at FTC-DCO 0402; CX 24 at FTC-DCO 0418).

252. The page immediately following the 7 Herb Formula product description set forth in F. 251 displays a heading in large, highlighted and bold type:

Heartburn?
Acid Reflux?
Esophageal Cancer?

Immediately below that heading is italicized text which includes the statement: "The herbs in 7*Herb Formula . . . improve digestion, gall bladder, and bowel function, cleanse and

detoxify the body, heal ulcers anywhere, and may prevent and even heal cancer. Be in control, don't be a victim!" (CX 23 at FTC-DCO 0403; CX 24 at FTC-DCO 0419) (emphasis in original).

253. The Cancer Newsletter contains testimonials specifically referring to 7 Herb Formula. The headings for these testimonials are each in highlighted, large, bold type and include the following: "**7 Herb Formula battles cancer**" (CX 23 at FTC-DCO 0393; CX 24 at FTC-DCO 0409; *see* F. 184) (emphasis in original); "**7 Herb eliminates pre-cancerous growth**" (CX 23 at FTC-DCO 0394; CX 24 at FTC-DCO 0410) (emphasis in original); and "**7 Herb Formula helps battle cancer**" (CX 23 at FTC-DCO 0398; CX 24 at FTC-DCO 0414, describing a single father diagnosed with a prostate tumor who "began taking the 7 Herb and shark cartilage. . . . Within 60 days, . . . PSA level dropped from 256 to 5. . . . [Thereafter, n]o evidence of . . . tumor.") (emphasis in original).

254. The logo for 7 Herb Formula is the only product logo featured in the Cancer Newsletter. In addition to appearing on the 7 Herb Formula product page, the logo appears on the last page of the Cancer Newsletter, under the reminder, "REMEMBER! How to fight cancer is your choice!" (CX 23 at FTC-DCO 0405; CX 24 at FTC-DCO 0421).

255. The overall net impression from the Cancer Newsletter is that 7 Herb Formula inhibits tumors and is effective in the prevention,

treatment, or cure of cancer. (F. 195, 197-202, 251-54).

e. BioMolecular Nutrition Product Catalog

256. In DCO's BioMolecular Nutrition Product Catalog, the text next to pictures of the 7 Herb Formula bottle states that the herbs in 7 Herb Formula "purify the blood and promote cell repair, clear skin, cleanse the liver, decrease cell mutation, [and] fight pathogenic bacteria and tumor formation." (CX 17 at FTC-DCO 0061).

257. The phrase, "fight . . . tumor formation," used in the product description for 7 Herb Formula in the BioMolecular Nutrition Product Catalog, as set forth in F. 256, strongly implies that the 7 Herb Formula inhibits tumor formation. Combined with the additional phrases in the description, "promote cell repair," "decrease cell mutation," and "fight pathogenic bacteria," the words of the product description as a whole imply that 7 Herb Formula is effective in treating cancer.

258. The overall net impression from the portion of the BioMolecular Nutrition Product Catalog relating to 7 Herb Formula is that 7 Herb Formula inhibits tumors and is effective in the prevention, treatment, or cure of cancer. (F. 256-57).

259. The DCO advertising regarding 7 Herb Formula, referred to in F. 237-38, 240-44, 246-47, 249, 251-54, and 256, makes claims that relate to

consumer health. (F. 239, 245, 248, 250, 255, 257-58).

f. Radio Show

260. During the July 8, 2008 DCO HealthWatch radio program, in response to a caller's concern about colon cancer and question about whether the caller should follow her doctor's recommendation of a colonoscopy, James Feijo stated, "Polyps are nothing. . . . Polyps should be left alone." In addition, in response to the caller's question about taking 7 Herb Formula, Patricia Feijo stated "It's a good idea for anyone to take a little bit every day, you know, as a preventive, sure." (CX 5 at FTC-DCO 0562-66).

261. During the July 14, 2008 DCO HealthWatch radio program, Patricia Feijo stated that 7 Herb Formula is "great for cancer." (CX 8 at FTC-DCO 0691).

4. GDU

a. DCO Website

262. CX 14, a printout of the webpage for GDU on the DCO Website, is Exhibit C to the Complaint. CX 14A is another depiction of the same product webpage as CX 14, but captured so as to show the entire width of the page. (CX 14; CX 14A).

263. The webpage content for GDU on the DCO Website begins with a heading, in bold type, "**Immune Boosters**." Underneath that heading

is a picture of bottles of GDU, and under that, is a phrase, in small print, "Supplemental Facts." The product description that follows includes the heading in bold type, "**GDU – Arthritis Pain Anti Inflammatory**" and opens with the following paragraph:

> Contains natural proteolytic enzymes (from pineapple source bromelain) to help digest protein – even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation.

(CX 14 at FTC-DCO 0028; CX 14A at FTC-DCO 2844A). James and Patricia Feijo both took credit for writing this statement. (R 15 (J. Feijo, Dep. at 138-39); R 16 (P. Feijo, Dep. at 185-86)). Following this statement are several paragraphs describing the ingredients of GDU and its "wide range of actions . . . that make it suited to a wide range of uses." Among these promoted uses is "as an adjunct to cancer therapy." (CX 14 at FTC-DCO 0028).

264. The description of GDU on the product webpage on the DCO Website, as set forth in F. 263, implies that GDU inhibits tumors and is a cancer treatment.

265. At the side of the GDU product webpage is a link to "buy now." Below that, is the instruction: "Read our clients [sic] testimonials on using this anti inflammatory," and links to subjects including arthritis, injuries, and spinal stenosis. Also included are links to "Breast Mass" and "Prostate Cancer." (CX 14A).

266. The DCO webpage "Cancer News," which makes representations regarding the Challenged Products as a group (F. 180-88), states: "If you suffer from any type of cancer, Daniel Chapter One suggests taking" several DCO products, including GDU. A prominent picture of a bottle of GDU follows, adjacent to which is the statement in bold type, "**Daniel Chapter One's Cancer solutions**." Under the picture, the text states:

> **To Buy the products click here**
>
> **How to fight cancer is your choice!**

(CX 13 at FTC-DCO 0013-14; CX 13A) (emphasis in original).

267. A testimonial entitled "Breast Mass," linked to the Cancer News webpage on the DCO Website, states:

> I went in for a breast examination by mammography. On 10/8/01 they said they found a mass that they believed was not cancerous, but benign. I began taking GDU six times a day: 2 before breakfast, 2 before lunch, and 2 before dinner, and in a month I went to my doctor for the breast examination, and he found nothing on either breast. Around that time I got another bottle of GDU and the Superior Herbal Fat Burners, which I took twice a day. In April I had my 6-month examination and the letter read: "We are pleased to

> inform you that the results of your recent breast evaluation are normal."

(CX 13 at FTC-DCO 0024; *see also* CX 17 at FTC-DCO 0101 (same)).

268. There are testimonials linked to the Cancer News webpage that specifically refer to GDU, including: "Nancy – Cured Breast Cancer in 3 months – 7 Herb and GDU"; and "Mel – Breast Mass [illegible] and GDU." (CX 13 at FTC-DCO 0014).

269. The overall net impression of the DCO Website content relating to GDU is that GDU inhibits tumors and is an effective treatment for cancer. (F. 180, 187, 189, 262-63, 265-68).

b. BioGuide

270. The product pages devoted to GDU in DCO's BioGuide begin with the following statement: "**GDU:** Contains natural proteolytic enzymes (from pineapple source bromelain) to help digest protein – even that of unwanted tumors and cysts." (CX 21 at FTC-DCO 0329) (emphasis in original). This same statement is repeated on the following page. (CX 21 at FTC-DCO 0330).

271. On the first page devoted to GDU in the BioGuide is a paragraph describing a variety of uses for GDU, which include "as an adjunct to cancer therapy." Immediately below this section is text in large, colored type, "**to help digest protein even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation.**"

Immediately below this statement is a headline in large, bold, colored type, "**Prostate Cancer**," along with a picture of a smiling man. (CX 21 at FTC-DCO 0330) (emphasis in original). On the following page is a headline in large, bold, colored type, "**Breast Mass**," adjacent to a photograph of a smiling woman. (CX 21 at FTC-DCO 0331) (emphasis in original).

272. The description of GDU in the BioGuide implies that GDU inhibits tumors. (F. 270-71).

273. The testimonial in the BioGuide entitled "Breast Mass" includes the following text:

> I went in for a breast examination by mammography. On 10/8/01 they said they found a mass that they believed was not cancerous, but benign. I began taking GDU six times a day: 2 before breakfast, 2 before lunch, and 2 before dinner, and in a month I went to my doctor for the breast examination, and he found nothing on either breast. Around that time I got another bottle of GDU and the Superior Herbal Fat Burners, which I took twice a day. In April I had my 6-month examination and the letter read: "We are pleased to inform you that the results of your recent breast evaluation are normal."

At the conclusion of the testimonial, the following excerpt appears in large, bold, green type:

> ***'We are pleased to inform you that the results of your recent breast evaluation are normal.'***

(CX 21 at FTC-DCO 0331) (emphasis in original).

274. In DCO's BioGuide there is a testimonial under a headline in large, bold, bright green type, "**Lowered PSA**." The testimonial states in pertinent part: "My GOOD NEWS is that my PSA went from 6.9 to 6.0 after I finished using my first four bottles of 7 Herb formula, in combination with your Bio C 1000, GDU and other minerals and vitamins. I believe it was your products that did the trick. . . ." (CX 21 at FTC-DCO 0353) (emphasis in original).

275. The overall net impression from the portions of the BioGuide relating to GDU is that GDU inhibits tumors and is an effective treatment for cancer. (F. 205, 207-11, 270-74).

c. Cancer Newsletter

276. The Cancer Newsletter includes a feature on GDU, with a picture of a GDU bottle next to a headline in large, bold type, "**Enzymes attack growths**." The opening paragraph states:

> Daniel Chapter One GDU Caps contains [sic] proteolytic enzymes that metabolize protein and can aid the body in breaking down a tumor. **The importance of oral enzymes in treating cancers has been the subject of scholarly papers and books**

> **for almost a century. . . . Enzymes, according to researchers, can change leukemia cells, returning those cells to a normal state. Enzymes have been shown to induce T cells and tumor necrosis factor.** The enzymes, while helping to destroy cancer cells, are not toxic, unlike other forms of treatment currently being imposed on cancer patients. . . . Daniel Chapter One GDU Caps contains [sic] proteolytic enzymes that God created to break up an excess protein mass and can aid the body in eliminating a tumor."

(CX 23 at FTC-DCO 0399; CX 24 at FTC-DCO 0415) (emphasis in original). Adjacent to the GDU headline, photograph, and text are two testimonials with headlines in large, highlighted and bold type, "**Lump is gone without dangerous surgery**" and "**Cancer Success a Lie!**" (CX 23 at FTC-DCO 0399; CX 24 at FTC-DCO 0415) (emphasis in original).

277. The phrases "treating cancer," returning leukemia cells "to a normal state," and "helping to destroy cancer cells," in the product description for GDU in the Cancer Newsletter, as set forth in F. 276, imply that GDU treats cancer.

278. The overall net impression from the Cancer Newsletter is that GDU inhibits tumors and is an effective treatment for cancer. (F. 195, 197, 199-200, 202).

d. BioMolecular Nutrition Product Catalog

279. DCO's BioMolecular Nutrition Product Catalog states, next to pictures of GDU bottles, that GDU "[c]ontains natural proteolytic enzymes (from pineapple source bromelain) to help digest protein, even that of unwanted tumors and cysts. Helps to relieve pain, inflammation, and as an adjunct to cancer therapy." (CX 17 at FTC-DCO 0062).

280. The language of the product description for GDU in the BioMolecular Nutrition Product Catalog, as set forth in F. 279 implies, that GDU inhibits tumors and is an effective treatment for cancer.

281. The overall net impression from the portion of the BioMolecular Nutrition Product Catalog relating to GDU is that GDU inhibits tumors and is an effective treatment for cancer. (F. 279).

282. The DCO advertising regarding GDU, referred to in F. 262-63, 265-68, 270-71, 273-74, 276, and 279, makes claims that relate to consumer health. (F. 264, 269, 272, 275, 277-78, 280-81).

5. BioMixx

a. Website advertising

283. The www.danielchapterone.com webpage, "Cancer News," which makes representations regarding the Challenged Products as a group (F. 180-88) states: "If you suffer from any type of cancer, Daniel Chapter One suggests taking" several

DCO products, including BioMixx ™. A prominent picture of a bottle of BioMixx follows, adjacent to which is a statement in bold type, "**Daniel Chapter One's Cancer solutions**." Under the picture, the text states:

> **To Buy the products click here**
>
> **How to fight cancer is your choice!**

(CX 13 at FTC-DCO 0013-14; CX 13A) (emphasis in original).

284. The www.danielchapterone.com Cancer News webpage includes the following testimonial, accompanied by a photograph of a smiling woman:

> *Tracey was given no hope!*
>
> The doctors had pretty much given up on Tracey. She had leukemia and tumors on the brain, behind the heart and on her liver.
>
> . . . .
>
> I had contracted leukemia and had three inoperable tumors. When I decided not to do chemotherapy or radiation, my father sent me Bio*Mixx and 7 Herb Formula. Each day as I took it and got it into my system more and more, the better I felt. Then I added Garlic Pur, Siberian Ginseng, and Bio*Shark. I am now in complete remission. The cancer cell count has dropped, the doctors tell me: I had

> a tumor just above the brain stem in my brain that has completely disappeared. The tumor on my liver is shrinking and the tumor behind my heart has shrunk over 50%. . . .

(CX 13 at FTC-DCO 0016) (emphasis in original).

285. BioMixx is promoted along with the other Challenged Products on the DCO website www.dc1pages.com, where the following text appears:

> **Supporting Products**
>
> To enhance 7 Herb Formula's healing quantities Daniel Chapter One advises to get familiar with the supporting products below:

Immediately below that text is a photograph of bottles of each of the Challenged Products. Adjacent to the photograph, in bold print, the following appears:

> **CANCER TREATMENT:**
>
> **7Herb Formula**
> **Bio*Shark**
> **BioMixx**
> **GDU Caps**

(CX 18 at FTC-DCO 0190) (emphasis in original).

286. The overall net impression from the website content for BioMixx described in F. 283-85 is

that BioMixx is effective in the prevention, treatment, or cure of cancer.

b. BioGuide

287. The product description for BioMixx in DCO's BioGuide includes the statements:

> Helps detoxify the body, boosts immunity and energy. . . . What separates BioMixx is that it was developed specifically to maximize the immune system, particularly for those individuals whose immune systems were compromised through chemotherapy and radiation. BioMixx . . . is the most powerful, most advanced formula ever developed for strengthening and building the immune system. . . . This scientifically designed formula provides your body with . . . nutrients . . . for cell, organ, and tissue health necessary for a healthy immune system. Whether you're losing weight battling illness, or are weakened due to intense training, BioMixx is the best.

(CX 21 at FTC-DCO 0334).

288. The language of the product description for BioMixx in DCO's BioGuide, as set forth in F. 287, clearly implies that BioMixx is an effective treatment for the adverse effects of chemotherapy and radiation.

289. DCO's BioGuide refers to BioMixx in the testimonial entitled "**Cancer Brain Tumor**."

(F. 204; *see* CX 21 at FTC-DCO 0353 (emphasis in original)).

290. DCO's BioGuide refers to BioMixx in the testimonial entitled "**Prostate Cancer**." This headline, in large, bold type appears next to a picture of a smiling man. The testimonial states in pertinent part: "I had beam radiation for prostate cancer. I also took 7 Herb Formula, 6 ounces a day, and BioMixx; I never had a bad day, never felt sick. When my PSA went from 7.6 to 0.5 in the month after I finished radiation, my doctor was surprised. Several months later it was down to 0.16!" (CX 21 at FTC-DCO 0330) (emphasis in original).

291. The overall net impression from the portions of the BioGuide relating to BioMixx is that BioMixx is effective in the treatment of cancer and that BioMixx heals the adverse effects of radiation and chemotherapy. (F. 204, 208, 211, 297-90).

c. Cancer Newsletter

292. The Cancer Newsletter refers to BioMixx in the testimonial "7 Herb Formula Battles Cancer." This testimonial states in part: "I had contracted leukemia and had three inoperable tumors. When I decided not to do chemotherapy or radiation, my father sent me Bio*Mixx and 7 Herb Formula. Then I added Garlic, Siberian Ginseng, and Bio*Shark. I am now in complete remission." (CX 23 at FTC-DCO 0393; CX 24 at FTC-DCO 0409).

293. The Cancer Newsletter includes the following statements in the product description of BioMixx: "Bio*Mixx boosts the immune system, cleanses the blood and feeds the endocrine system to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments." (CX 23 at FTC-DCO 0400; CX 24 at FTC-DCO 0416).

294. The overall net impression from the Cancer Newsletter is that BioMixx is effective in the treatment of cancer and that BioMixx heals the adverse effects of radiation and chemotherapy. (F. 195, 197, 200, 202, 292-93).

295. The DCO advertising regarding BioMixx, referred to in F. 283-85, 287, 289-90, and 292-93, makes claims that relate to consumer health. (F. 286, 288, 291, 294).

6. Disclaimers

296. On the DCO Website, at the very end of the content, at the bottom of the webpage, a copyright notice appears. Within the notice, after the copyright language, the following language appears:

> The information on this website is intended to provide information, record, and testimony about God and His Creation. It is not intended to diagnose a disease. The information provided on this site is designed to support, not replace, the relationship that exists

> between a patient/site visitor and his/her health care provider. Caution: some herbs or . . . supplements should not be mixed with certain medications.

The above quoted statement appears in type font that is significantly smaller than the type font used for other content on the DCO Website. (CX 12 at FTC-DCO 0012; CX 13 at FTC-DCO 0027; CX 14 at FTC-DCO 0030).

297. At the bottom of the "checkout" page, located at www.dc1store.com, to which individuals are directed for purchasing a DCO product, there appears a copyright notice. Within the notice, after the copyright language, the following language appears:

> The information on this website is intended to provide information, record, and testimony about God and His Creation. It is not intended to diagnose a disease. The information provided on this site is designed to support, not replace, the relationship that exists between a patient/site visitor and his/her health care provider. Caution: some herbs or . . . supplements should not be mixed with certain medications.

The above quoted statement appears in type font that is approximately the same size as the type font used for most of the other content on the checkout page. (CX 11 at FTC-DCO 0712-0713).

298. At the end of the BioGuide, before the index, in the lower right hand corner is a bordered text box. Inside the box, after a notice of copyright paragraph, the next paragraph states:

> This catalog is intended to provide information, record, and testimony about Y'shua and His Creation. It is not intended to diagnose or treat disease. Caution: some herbs should not be mixed with certain medications.

The above quoted statement appears in type font that is significantly smaller than the type font used for most other content in the BioGuide. (CX 21 at FTC-DCO 0377).

299. At the bottom of the last page of the Cancer Newsletter, in the lower right hand corner, there is a copyright notice paragraph, and thereafter, the following text:

> The information on this website is intended to provide information, record, and testimony about God and His Creation. It is not intended to diagnose or treat disease. Caution: some herbs or supplements should not be mixed with certain medications.

The above quoted statement appears in type font that is tiny in relation to the type font used for other content in the Cancer Newsletter, and is nearly illegible. (CX 23 at FTC-DCO 0405; CX 24 at FTC-DCO 0421).

300. At the bottom of certain webpages from www.dc1pages.com, at the very end of the web

content, a copyright notice appears. Within the notice, after the copyright language, there is the following language:

> The information on this website is intended to provide information, record, and testimony about Y'shua and His Creation. It is not intended to diagnose or treat disease. The information provided on this site is designed to support, not replace, the relationship that exists between a patient/site visitor and his/her health care provider. Caution: some herbs . . . should not be mixed with certain medications.

The above quoted statement appears in type font that is significantly smaller than the type font used for other content on www.dc1pages.com. (CX 18 at FTC-DCO 0133, 0189; *see also* CX 30 at FTC-DCO 0496).

301. Some product ordering pages on the website www.dc1store.com contain the following language in italicized type:

> **These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent disease.*

The above quoted statement appears in type font that is approximately the same size as the type font used for other content on the product pages. (CX 17 at FTC-DCO 0073, 0076, 0080, 0084, 0089, 0095, 0098).

302. "The Most Simple Guide" contains no language disclaiming any intent to diagnose or treat disease. (CX 20).

303. Where disclaimer language does appear in the websites, BioGuide, and Cancer Newsletter, it appears in a font size that is equal to or significantly smaller than that used for other written material. (F. 297-299, 301-02). In the Cancer Newsletter, "How to fight Cancer is Your Choice!!!" the quoted disclaimer language is infinitesimal in relation to the other written material. (F. 300).

304. In the pages from the website www.dc1pages.com (CX 18 at FTC-DCO 0133, 0189), the sentence purporting to disclaim any intent to "treat" disease was followed on the next page by a statement touting, in far larger type font:

> **CANCER** TREATMENT
>
> **7 Herb Formula**
> **Bio*Shark**
> **BioMixx**
> **GDU Caps**

(CX 18 at FTC-DCO 0190).

305. The purported disclaimers are ambiguous and inconspicuous in relation to other messages conveyed by the advertisements. (F. 296-301, 303-04).

306. The purported disclaimers do not alter the overall net impression from the advertisements that the Challenged Products prevent, treat, or cure cancer. (F. 296-301, 303-04).

F. Substantiation for DCO's Advertising Claims

1. Testing of the Challenged Products

307. Respondents represented that they possessed and relied upon a reasonable basis that substantiated the DCO advertising claims at the time they were made. (Answer ¶ 15).

308. Respondents did not conduct or direct others to conduct any scientific testing of the effects of the Challenged Products. Respondents are not aware of any such testing having been performed by others. (CX 39 (Respondents' Answer to Interrogatory 15); R 16 (P. Feijo, Dep. at 161); R 15 (J. Feijo, Dep. at 201-02); P. Feijo, Tr. 405).

309. Respondents conducted no scientific testing on BioShark. (P. Feijo, Tr. 405; R 16 (P. Feijo, Dep. at 161)).

310. Universal Nutrition, the manufacturer of BioShark, did not conduct any testing on BioShark. (R 17 (Bauhoffer-Kinney, Dep. at 45-46)).

311. Respondents never had an outside lab study the components of 7 Herb Formula to determine its effects. (R 16 (P. Feijo, Dep. at 132)).

312. GDU was never subjected to clinical trials and Respondents have not conducted any studies to see whether GDU would counteract with any conventional cancer medicine someone might also be taking. (R 16 (P. Feijo, Dep. at 190, 194)).

313. Respondents did not conduct any tests or clinical studies on BioMixx and did not engage anybody else to do any kind of clinical tests on BioMixx. (R 16 (P. Feijo, Dep. at 199)).

314. Universal Nutrition, the manufacturer of BioMixx, has not conducted any testing on BioMixx. (R 17 (Bauhoffer-Kinney, Dep. at 50)).

315. It was not Respondents' practice to obtain scientific studies about any of the components in their products. (R 16 (P. Feijo, Dep. at 120)).

316. Respondents' basis for making their claims about the Challenged Products includes personal observations and customer testimonials. (R 15 (J. Feijo, Dep. at 141); R 16 (P. Feijo, Dep. at 116, 132, 186-87, 199)).

317. Respondents' substantiation for their claims regarding BioShark includes an article by I. W. Lane entitled "Sharks Don't Get Cancer." (R 16 (P. Feijo, Dep. at 161-62)).

318. Respondents relied upon a variety of materials, books, magazines, and articles, which James and Patricia Feijo had read, which provided them with an understanding of how certain substances in the Challenged Products could be utilized to help healing. (R 15 (J. Feijo, Dep. at 176-86); P. Feijo, Tr. 605-08; R 10).

319. The reference materials relied upon by Respondents do not constitute adequate substantiation for a claim that any of the Challenged Products prevent, treat, or cure cancer. (F. 326, 328, 343-49, 362, 365-67, 368-69, 372, 376, 383).

2. Summary of proffered experts' testimony on substantiation

a. Complaint Counsel's proffered expert

(1) Qualifications

320. Dr. Denis Miller ("Miller"), who was called to testify as an expert for Complaint Counsel, is a board-certified pediatric hematologist/oncologist. (Miller, Tr. 29; Expert Report of Denis R. Miller, M.D., dated Jan. 28, 2009, (hereinafter referred to as CX 52 (Miller Report) at ___) at 1).

321. For over forty years, Miller has directed clinical care, education, laboratory and clinical research, and administration, heading divisions or departments at University of Rochester Medical Center, New York Hospital-Cornell Medical Center, Memorial Sloan-Kettering Cancer Center, and Northwestern University Medical School. (CX 52 (Miller Report) at 1).

322. Miller also has served as Associate Medical Director of Cancer Treatment Centers of America ("CTCA") and as Scientific Director of CTCA's Cancer Treatment Research Foundations. (CX 52 (Miller Report) at 1).

323. As Scientific Director, Miller supervised the clinical research program and was principal investigator for a number of Phase I/II clinical studies involving treatments for hematological malignancies and cancers of the head and neck, lung, breast, pancreas, and colon. (CX 52 (Miller Report) at 1-2).

324. Miller has authored or co-authored over 300 book chapters, peer-reviewed articles, and abstracts, and has served on the editorial boards of the British Journal of Hematology and the American Journal of Clinical Oncology. (CX 52 (Miller Report) at 3).

325. Miller currently is the Oncology/Hematology Therapeutic Area Leader at PAREXEL International, a leading contract research organization, where he manages clinical trials for the pharmaceutical industry. (CX 52 (Miller Report) at 2).

326. Based on his training, experience, and familiarity with this area of research, Miller is qualified to give expert opinions in the area of cancer, cancer research, and research methodology. (F. 320-25).

(2) Scope of work and materials considered

327. Miller was asked to determine whether there is competent and reliable scientific evidence to substantiate the following claims: BioShark inhibits tumor growth; BioShark is effective in the treatment of cancer; 7 Herb Formula is effective in the treatment or cure of cancer; 7 Herb Formula inhibits tumor formation; GDU eliminates tumors; GDU is effective in the treatment of cancer; BioMixx is effective in the treatment of cancer; and BioMixx heals the destructive effects of radiation and chemotherapy. (CX 52 (Miller Report) at 4).

328. To form his opinions, in addition to drawing upon his expertise in cancer care and treatment, Miller conducted literature searches, including searches in PubMed, Google, PDQ, NCI, MSKCC, MD Anderson Cancer Center, Dana Farber Cancer Institute, Search Medica, Stanford HighWire, Clinical Trials.gov, and many cancer and hematology journals such as the Journal of Clinical Oncology, Clinical Cancer Research, Blood, British Journal of Haematology, Supportive Care in Oncology, American Journal of Oncology, and the New England Journal of Medicine. Miller also reviewed materials provided by Complaint Counsel, including the Complaint and the DCO advertising attached to the Complaint as exhibits A through D, DCO advertising on www.danielchapterone.com, the BioGuide, the labels for the Challenged Products, and thirty testimonials regarding DCO products. Miller also reviewed the materials Respondents stated that they relied upon for substantiation. (CX 52 (Miller Report) at 5-7).

b. Respondents' proffered experts

(1) Qualifications

329. Respondents proffered five individuals as expert witnesses: James Duke, Ph.D.; Sally LaMont, N.D.; Rustum Roy; James Dews; and Jay Lehr, Ph.D.

330. Dr. Duke ("Duke") is a retired economic botanist. He has compiled and maintains a database which includes the chemical composition

("phytochemicals") of approximately 3,000 species of herbs, and codes the nature and extent of published data indicating biological actions for those chemicals. The data ranges from folklore, to animal or in vitro evidence, to approval of the chemical for those biological actions by foreign bodies referred to as Commission E or the Tramil Commission. (Duke, Tr. 476-78; R 18 (Duke, Dep. at 59, 91, 93, 118-19)).

331. Dr. LaMont ("LaMont") is a licensed naturopathic doctor and acupuncturist. Naturopathic doctors focus on primary prevention of illness and on stimulating the body's innate healing capacities to treat the underlying causes of disease. Naturopathic doctors, including LaMont, commonly use herbs in their practice. (LaMont Tr. 539, 541-42). LaMont also works with mind-body therapies and regularly suggests meditation, qigong, yoga, and other biofeedback-type of therapies that would strengthen the connection between a person's mind and immune system. (R 22 (LaMont, Dep. at 20)).

332. Rustum Roy ("Roy") is a scientist and an educator in the physical sciences and in integrative medicine. (Expert Report of Rustum Roy, dated Feb. 4, 2009 (hereinafter referred to as R 5 (Roy Report) at ___) at 2).

333. James Dews ("Dews") is a manufacturer of pharmaceuticals and "nutraceuticals," which Dews described as a merger of food supplements and pharmaceuticals. A nutraceutical can be created by extracting the chemical compounds from a food supplement. He helped create

and manufacture the product that eventually became 7 Herb Formula. (R 19 (Dews, Dep. at 17-18, 34-36, 76)).

334. Jay Lehr ("Lehr") is a Ph.D. environmental scientist and has written a book on health and fitness. (R 21 (Lehr, Dep. at 9-10)). Lehr has known James Feijo for approximately ten years and takes the Daniel Chapter One products PrePost, Endeurosine, and Mito/ATP to enhance his athletic performance. He has also recently begun taking GDU for his arthritic hip. (R 21 (Lehr, Dep. at 16-18)).

335. None of Respondents' proffered experts is a medical doctor. (F. 329-34; *see also* R 18 (Duke, Dep. at 56); Duke, Tr. 521; R 20 (Roy, Dep. at 26); R 5 (Roy Report) at FTC-DCO 234-36; Expert Report of James Dews, dated Feb. 4, 2009 (hereinafter R 6 (Dews Report) at ___) at 1-3; Expert Report of Jay Lehr (undated) (hereinafter referred to as R 21 (Lehr Report) at ___) at 1-2)).

336. None of Respondents' proffered experts has specialized training or experience regarding cancer or cancer treatment. (R 18 (Duke, Dep. at 19, 56); Duke, Tr. 521; R 22 (LaMont, Dep. at 11-12); LaMont, Tr. 576-77; *see generally* R 5 (Roy Report) at FTC-DCO 0234-36; R 6 (Dews Report) at 1-3; R 21 (Lehr Report) at 1-2).

337. None of Respondents' proffered experts has conducted clinical studies regarding cancer treatments. (R 18 (Duke, Dep. at 55); R 22 (LaMont, Dep. at 184); LaMont, Tr. 577; R 20 (Roy, Dep.

at 14); R 21 (Lehr, Dep. at 34); R 19 (Dews, Dep. at 61-63)).

(2) Scope of work and materials considered

338. None of Respondents' proffered experts reviewed the DCO advertising claims at issue in the case in preparing their opinions. (R 18 (Duke, Dep. at 36-37); Duke, Tr. 534; R 22 (LaMont, Dep. at 32-34, 56-58, 77-78); R 5 (Roy Report) at 1, FTC-DCO 0238-99; R 20 (Roy, Dep. at 7); R 6 (Dews Report) at 7-8; R 19 (Dews, Dep. at 36-38); R 21 (Lehr Report) at 2-4).

339. Respondents did not ask their proffered experts to render an opinion as to whether Respondents' purported substantiation materials constituted competent and reliable scientific evidence substantiating a claim that any of the Challenged Products prevent, treat, or cure cancer. (R 3 (Duke Report) at 1; R 4 (LaMont Report) at 3; R 5 (Roy Report) at 1; R 6 (Dews Report) at 2; R 21 (Lehr Report) at 2).

340. Respondents did not ask their proffered experts to render an opinion as to whether there existed any competent and reliable scientific evidence substantiating a claim that any of the Challenged Products prevent, treat, or cure cancer. (R 3 (Duke Report) at 1; R 4 (LaMont Report) at 3; R 5 (Roy Report) at 1; R 6 (Dews Report) at 2; R 21 (Lehr Report) at 2).

341. Respondents' proffered experts did not opine as to whether there is competent or reliable

scientific evidence substantiating a claim that any of the Challenged Products prevent, treat, or cure cancer. (R 3 (Duke Report) at 1, 3; R 4 (LaMont Report) at 3, 40; R 5 (Roy Report) at 1; R 6 (Dews Report) at 2, 14; R 21 (Lehr Report) at 2).

342. None of Respondents' proffered experts reviewed the DCO advertising claims at issue in the case in preparing their opinions. (R 18 (Duke, Dep. at 36-37); Duke, Tr. 534; R 22 (LaMont, Dep. at 32-34, 56-58, 77-78); R 5 (Roy Report) at 1, DCO 0238-99; R 20 (Roy, Dep. at 7); R 6 (Dews Report) at 7-8; R 19 (Dews, Dep. at 36-38); R 21 (Lehr Report) at 2-4).

3. Level of substantiation required to support anti-cancer effects

343. "Competent and reliable scientific evidence" is required to conclude that a cancer treatment is effective. (Miller, Tr. 66-68).

344. Competent and reliable scientific evidence means in part that a hypothesis has been established. To constitute competent and reliable scientific evidence that a product treats, cures, or prevents cancer, the product's efficacy and safety must be demonstrated through controlled clinical studies. (CX 52 (Miller Report) at 7; *see also* LaMont, Tr. 596 (stating that the definition of competent and reliable scientific evidence includes a "spectrum" of evidence, such as studies of animals and cell culture lines, but that investigation into a compound's safety and efficacy progresses

"towards clinical outcome studies in an office-based practice or a university setting, and eventually moves towards human clinical trials")).

345. Clinical studies are studies on humans. Non-clinical studies are performed in test tubes and in animals with the aim of demonstrating potential activity and acceptable safety. Once non-clinical studies have been performed, the study proceeds into progressive phases of clinical trials in humans. (CX 52 (Miller Report) at 9).

346. Only data from well-designed, controlled, clinical trials will substantiate a claim that a new therapy is safe and effective to treat, cure, or prevent cancer. (CX 52 (Miller Report) at 30).

347. The proper format for any clinical trial protocol includes the following: Details of the rationale for the study; clear elucidation of primary and secondary objectives; clear presentation of the investigation plan, including study design, selection of subjects, study treatments, documentation of prior and concomitant illnesses and treatments, and study procedures; description of specific methods of data collection, quality assurance, and quality control; description of statistical procedures; reporting of studies of pharmacokinectics, pharmacodynamics, quality of life, and health economics; discussion of overall conclusion regarding safety and efficacy; relevant references; tables and figures; selected subject listings of demographics, disease and treatment parameters, endpoints, safety factors, and deaths; and subject narratives for

serious adverse events and deaths. (CX 52 (Miller Report) at 8-9; Miller Tr. 66-68).

348. Claims that a dietary supplement prevents cancer, aids in the treatment of cancer, or can be used as a primary treatment for cancer, as opposed to claims that a dietary supplement is good nutrition, require substantiation. (Miller, Tr. 152).

349. Anti-cancer agents may work by preventing cell proliferation (division), inducing programmed cell death (apoptosis), inhibiting growth factors or biochemical pathways that result in cell death, and inhibiting new blood vessel formation (angiogenesis). Anti-angiogenic agents have an important role in the treatment of some types of cancer. (CX 52 (Miller Report) at 10).

350. The process required to prove that a drug is safe and effective for the treatment of disease is very costly. Testing used to prove that a drug is a safe and effective treatment for disease is a particularly challenging and costly endeavor to undertake for testing herbal products, because it is difficult to extract and test a single chemical component from an herb, and because an herb may comprise thousands of chemical components. (Miller, Tr. 181; Duke, Tr. 499-502, 537-38; *see also* LaMont, Tr. 596-97).

351. Testimonials do not substitute for a well-designed clinical trial. (CX 52 (Miller Report) at 30).

352. Anecdotal reports are the weakest form of evidence to support the anti-cancer activity of a new agent. (CX 52 (Miller Report) at 11-12).

353. Testimonials have very little scientific validity. In the thirty testimonials reviewed by Miller, many of the patients were taking other modalities of anti-cancer therapy. There was insufficient documentation that the individuals had cancer. There was no valid instrument to measure their reported response to the Challenged Products. A patient's report that he or she "felt better," standing alone, does not scientifically measure the patient's response. (Miller, Tr. 141-42, 214-15).

4. Potential harm from alternative or ineffective remedies

354. The need to substantiate a claim of anti-cancer activity with competent and scientific evidence is the same whether the purported agent is an herbal medicine or a conventional pharmaceutical agent. "There [are] not . . . two kinds of medicine. There's not conventional medicine and alternative medicine. There's one medicine, medicine that works. The other medicine may or may not work, but to show that it works you have to go through the process. . . . [T]here shouldn't be a separate, different, less rigorous way of identifying the safety and the efficacy of so-called complementary medicine just because it's complementary. It has to go through the same process because we want to help cancer patients and we want to make sure

that what they're getting is safe and effective." (Miller, Tr. 144).

355. Effective complementary medicine adds to the efficacy of standard anti-cancer therapy, reducing some of cancer therapy's adverse side effects (e.g., nausea and vomiting, severe neutropenia, anemia, fatigue), improving general well-being and quality of life, and permitting oncologists to administer effective doses of therapy on time. Many new targeted therapies work better when given with conventional anti-cancer therapy and rarely are as efficacious when given as single agents. Suggesting that complementary medicine can be an effective substitute for traditional medicine would be a disservice to cancer patients because delays in effective therapy may allow cancer cells to regrow, develop resistance to therapy, and metastasize. (CX 52 (Miller Report) at 11).

356. Taking the Challenged Products presents a potential harm. This is most acute if a cancer patient foregoes potentially beneficial and effective therapy and replaces that option with BioShark, 7 Herb Formula, GDU, or BioMixx, alone or in combination with other DCO products. Diagnosing cancer early and treating it appropriately and effectively still offers the best chance of curing it. The use of complementary or alternative therapies exclusively as front-line treatment will result in disease progression. (CX 52 (Miller Report) at 12).

357. The Challenged Products are not necessarily harmless simply because they are herbs as

opposed to drugs. Everything has potential side effects. One example is cat's claw, an ingredient in 7 Herb Formula. Cat's claw may have an effect on a very important enzyme system in the liver that causes either the breakdown of other drugs or may activate other drugs. As a result of this interaction, cat's claw might increase the concentrations of some drugs in the patient's system, which can lead to toxicity, or can cause an increased breakdown of those drugs, thereby lessening their efficacy. Cat's claw increases the activity of many drugs given for high blood pressure, which can result in hypotension (low blood pressure). Cat's claw can cause diarrhea, which is particularly adverse for a cancer patient who already may be nutritionally challenged. Cat's claw may also cause bleeding by affecting the blood's clotting system, thereby potentially increasing the risk of bleeding in a cancer patient. Thus, if a cancer patient is already taking a medication that lowers his or her platelet count or increases his or her risk of bleeding, this could be an extremely dangerous interaction. (Miller, Tr. 111-13).

358. Side effects are also affected by the dosing. One example of the importance of proper dosing is with Turkish rhubarb root, a component of 7 Herb Formula. Turkish rhubarb root contains tannins, which, in high doses, cause diarrhea and, in lower doses, cause constipation. (Miller, Tr. 117).

359. Another example of the importance of proper dosing comes from a study of parthenolide, the active ingredient in feverfew, a component

of GDU. The study was designed to determine through dose escalation what dose of parthenolide would show evidence of activity in cancer patients. Researchers were unable to measure any parthenolide in the bloodstream at the doses administered in the study. Even with very low doses, patients had side effects, including fever, chills, nausea, diarrhea, blurred vision, and fatigue. (Miller, Tr. 130-31).

360. An example of potentially harmful interactions was reported in a study of curcumin, the active ingredient in tumeric, a component of GDU. That study reported that curcumin can block or decrease the activity of a number of commonly used anti-cancer chemotherapy agents, including those used to treat breast cancer, colon cancer, and lymphoma. (Miller, Tr. 126).

361. Enhancing a deficient immune system is important. An over-enhanced immune system can be related to a number of autoimmune diseases, including malignancies like multiple myeloma. (Miller, Tr. 218-19).

5. No competent and reliable scientific evidence to substantiate claims about the Challenged Products, either alone or in combination with other DCO products

362. The reference materials relied upon by Respondents do not constitute competent and reliable scientific evidence that any of the Challenged Products prevent, treat, or cure cancer. (CX 52 (Miller Report) at 31; Miller Tr. 143).

363. There is no competent and reliable scientific evidence that the Challenged Products are effective, either alone or in combination with other DCO products, in the prevention, treatment, or cure of cancer, in inhibiting tumor formation, or in ameliorating the adverse effects of radiation and chemotherapy. (CX 52 (Miller Report) at 31; Miller Tr. 143).

364. Since BioShark, 7 Herb Formula, GDU, and BioMixx have not been tested, their effectiveness in the prevention, treatment, or cure of cancer is not known. (R 22 (LaMont, Dep. at 47-48); LaMont, Tr. 579-82).

365. The majority of the materials relied upon by Respondents as substantiation were not peer-reviewed papers. The materials did not include controlled clinical trials. The materials consisted of author opinions and reviews of literature on the use of herbal medicines for a number of different diseases, including cancer. (Miller, Tr. 81-82).

366. Many of the studies cited by Respondents as substantiation were non-clinical studies, i.e., in vitro or animal studies. (CX 52 (Miller Report) at 10).

367. Other studies relied upon by Respondents as substantiation evaluated isolated compounds that are present in some of the Challenged Products and showed nonspecific immunostimulatory activities or suggested cancer preventive effects. This does not substitute for an actual evaluation of each Challenged Product itself. It is not possible to extrapolate from

results of a published non-clinical study of curcumin that GDU can eliminate tumors. GDU itself, or each active ingredient in GDU, must be subjected to the same experimental conditions as those to which the curcumin was subjected. (CX 52 (Miller Report) at 11).

6. No competent and reliable scientific evidence to substantiate BioShark claims

368. The reference materials relied upon by Respondents do not constitute competent and reliable scientific evidence that BioShark inhibits tumor growth in humans or that it is effective in the treatment of cancer in humans. (CX 52 (Miller Report) at 13).

369. Respondents' reliance on Dr. I. William Lane's book, "Sharks Don't Get Cancer," was misplaced, as studies at Johns Hopkins University indicate that sharks do indeed get cancer. (CX 52 (Miller Report) at 16).

370. There have been no adequate and well-controlled studies demonstrating that BioShark is anti-angiogenic or is effective in the treatment of cancer, and even supporting non-clinical studies of crude or partially-purified shark cartilage products were extremely limited, particularly with regard to mechanisms of action, pharmacokinetics, pharmacodynamics, and dose response. (CX 52 (Miller Report) at 17).

371. There is no competent and reliable scientific evidence that any crude shark cartilage

product is effective in treating human cancer. (CX 52 (Miller Report) at 17).

7. No competent and reliable scientific evidence to substantiate 7 Herb Formula claims

372. The reference materials relied upon by Respondents do not constitute competent and reliable scientific evidence that 7 Herb Formula is effective in the treatment or cure of cancer or that it inhibits tumor formation. (CX 52 (Miller Report) at 18).

373. There is no competent and reliable scientific evidence that 7 Herb Formula is effective in the treatment or cure of cancer or that it inhibits tumor formation. (CX 52 (Miller Report) at 18).

374. There are no clinical or non-clinical studies supporting claims that 7 Herb Formula, or any of its individual ingredients, is an effective anti-cancer agent or inhibits tumor formation. (CX 52 (Miller Report) at 19).

375. There have been animal and in vitro studies on the ingredients in 7 Herb Formula: Burdock root, cat's claw, sheep sorrel, slippery elm bark, Turkish rhubarb root, Siberian ginseng, and watercress. There have been no controlled clinical trials on humans with cancer. (CX 52 (Miller Report) at 18-22).

8. No competent and reliable scientific evidence to substantiate GDU claims

376. The reference materials relied upon by Respondents do not constitute competent and reliable scientific evidence that GDU eliminates tumors or is effective in the treatment of cancer. (CX 52 (Miller Report) at 22).

377. There is no competent and reliable scientific evidence that GDU eliminates tumors or is effective in the treatment of cancer. (CX 52 (Miller Report) at 22).

378. There have been no randomized, controlled clinical trials of any of the individual components of GDU or of GDU itself in patients with cancer. (CX 52 (Miller Report) at 27).

379. Curcumin (tumeric), one of GDU's ingredients, is currently being evaluated in controlled clinical trials to determine its potential as a chemoprotective and cancer preventive agent. (CX 52 (Miller Report) at 22).

380. Some animal studies have suggested that curcumin may have activity as a cancer preventive and therapeutic agent. (CX 52 (Miller Report) at 23).

381. Some animal studies have also suggested that curcumin may actually inhibit the anti-cancer activity of some approved anti-cancer agents, as well as exacerbate iron deficiency. (CX 52 (Miller Report) at 27).

382. Further research on curcumin is necessary to determine if curcumin has cancer preventive

or chemotherapeutic effects. (CX 52 (Miller Report) at 27).

9. No competent and reliable scientific evidence to substantiate BioMixx claims

383. The reference materials relied upon by Respondents do not constitute competent and reliable scientific evidence that BioMixx is effective in the treatment of cancer or heals the destructive effects of radiation and chemotherapy. (CX 52 (Miller Report) at 27).

384. There is no competent and reliable scientific evidence that BioMixx is effective in the treatment of cancer or heals the destructive effects of radiation and chemotherapy. (CX 52 (Miller Report) at 27).

385. There are no reported studies that either BioMixx, or any of its constituent ingredients, is effective in the treatment of cancer in humans. (CX 52 (Miller Report) at 27-29).

386. There are absolutely no scientific data to support a statement that BioMixx assists the body in fighting cancer or in healing the destructive effects of radiation and chemotherapy treatments. (CX 52 (Miller Report) at 29).

10. Substantiation through competent and reliable scientific evidence for Respondents' claims about the efficacy of the Challenged Products was not addressed by Respondents' proffered experts

a. Duke

387. Duke was provided statements made by Respondents to review and was asked if the data he reviewed supported the accuracy of those statements. (Duke, Tr. 519). The statements he was given mirror selected statements from the product descriptions for the Challenged Products. (F. 238, 263, 293). Duke concluded:

> There is a reasonable basis for the claims that the ingredients of 7 Herb Formula "fights [sic] tumor formation, and fights [sic] pathogenic bacteria."
>
> There is a reasonable basis for the claims that the ingredients of GDU "contains [sic] natural proteolytic enzymes (from pineapple source bromelain) to help digest protein – even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation. . . . GDU is also used for . . . and as an adjunct to cancer therapy. GDU possesses a wide range of actions including anti-inflammatory and antispasmodic activity. . . ."

> There is a reasonable basis for the claims that the ingredients of BioMixx "boosts [sic] the immune system . . . to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments."

(R 3 (Duke Report) at 3; Duke, Tr. 519-21, 536).

388. Duke's opinions do not address whether competent and reliable scientific evidence is necessary to substantiate advertising claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 3 (Duke Report)).

389. Duke's opinions do not address whether there is competent and reliable scientific evidence to support advertising claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 3 (Duke Report)).

390. Duke's opinions do not address whether Respondents possessed and relied upon adequate substantiation to support their claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 3 (Duke Report)).

391. Duke does not recall seeing any articles that James or Patricia Feijo believe to have

substantiated the claims that Respondents made regarding the Challenged Products. (R 18 (Duke, Dep. at 185)).

392. Duke made no effort to determine whether there were any studies of any sort regarding the Challenged Products. (R 18 (Duke, Dep. at 190-91)).

393. Duke did not analyze any of the Challenged Products themselves, but instead analyzed only constituent ingredients of the Challenged Products. (Duke Tr. 524-27).

394. Duke did not know the concentrations of the ingredients contained in the Challenged Products. (Duke Tr. 533-34).

b. LaMont

395. LaMont was provided labels from the Challenged Products, and the substantiation evidence upon which Respondents relied to support statements reflected in the then-draft complaint, including claims that BioShark inhibits tumor growth, 7 Herb Formula is effective in treating and curing cancer, GDU eliminates tumors, and BioMixx is effective in treating cancer. (R 22 (LaMont, Dep. Exs. 1, 2)).

396. LaMont was asked to evaluate the labels and the substantiation evidence upon which Respondents relied, and to write a report that would describe the mechanism of action of some of the constituents of the Challenged Products. In addition to reviewing Respondents' substantiation evidence, LaMont reviewed published

medical literature in MedLine, PubMed, the Memorial Sloan-Kettering cancer website, and the American Botanical website, among other sources. (R 4 (LaMont Report at 3); LaMont, Tr. 549-550).

397. Based on her review, LaMont concluded:

> There is a reasonable basis to claim that the ingredients of GDU contain bromelain, a source of natural proteolytic enzymes from the pineapple, which helps digest unwanted proteins. GDU also contains tumeric, feverfew and quercitin, which help to reduce inflammation and relieve pain.
>
> Next, it is reasonable to claim that these ingredients as a whole may be used as an adjunct to cancer therapy, and that the ingredients possess a wide range of actions as anti-inflammatory agents.
>
> There is a reasonable basis to claim that the ingredients of 7 Herb Formula fight tumor formation, and fight pathogenic bacteria.
>
> There is a reasonable basis to claim that the ingredients of BioMixx boost the immune system, build lean body mass and support healing. It is also reasonable to claim that these ingredients assist the body in fighting cancer, cachexia and in healing the

destructive effects of radiation and chemotherapy treatments.

(R 4 (LaMont Report) at 40; LaMont, Tr. 572-74).

398. LaMont's opinions do not address whether competent and reliable scientific evidence is necessary to substantiate advertising claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 4 (LaMont Report)).

399. LaMont's opinions do not address whether there is competent and reliable scientific evidence to support advertising claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 4 (LaMont Report)).

400. LaMont's opinions do not address whether Respondents possessed and relied upon competent and reliable scientific evidence when Respondents made claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 4 (LaMont Report)).

401. LaMont did not analyze any of the Challenged Products themselves, but instead analyzed only the constituent ingredients of the Challenged Products. LaMont did not know the concentrations of the ingredients contained in any of the Challenged Products. (LaMont, Tr. 579, 582-83).

402. LaMont was unable to conclude that there was any evidence to support a claim that 7 Herb Formula is effective in treating or curing cancer. (R 22 (LaMont, Dep. at 205)).

403. LaMont was unable to conclude that BioMixx is itself effective in the treatment of cancer or that it heals the destructive effects of radiation and chemotherapy. (R 22 (LaMont, Dep. at 210-11))

c. Roy

404. Roy was asked to provide his opinion on the scientific validity of randomly controlled trials to evaluate whole-person healing; the science of homeopathy; and the scientific validity of traditional testing of herbal medicines. (R 5 (Roy Report) at 1).

405. Roy's conclusions included: Traditional randomly controlled double blind studies are inappropriate to evaluate whole-person healing approaches; whole-person healing approaches focus on the effect on the structure and function of the whole person, as opposed to the use of a drug to cure the symptoms of a disease; and cancer is a particular instance where whole-body healing approaches make more scientific sense than pharmaceutical approaches. (R 5 (Roy Report) at 1-2).

406. The bases for Roy's conclusions in F. 405 include his opinion that homeopathy was developed empirically, from observations of the effects of various different materials on the

functioning of healthy subjects, as opposed to trying a specific biochemical drug to cure a symptom. (R 5 (Roy Report) at 1-2).

407. The bases for Roy's conclusions in F. 405 include his opinion that herbal medicines have been tested epidemiologically by nature over thousands of years and hundreds of human generations, while pharmaceutical drug testing relies on statistical projections from small controlled trials. (R 5 (Roy Report) at 3-4).

408. Roy's opinions do not address whether there is competent and reliable scientific evidence to support Respondents' claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 5 (Roy Report)).

409. Roy's opinions do not address whether Respondents possessed and relied upon competent and reliable scientific evidence to support Respondents' claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 5 (Roy Report)).

410. Roy did not review the Complaint in this matter or any of the challenged advertisements. (R 20 (Roy, Dep. at 7)).

411. Roy is not an expert in homeopathy. (R 20 (Roy, Dep. at 12)).

412. Roy has no idea what ingredients the Challenged Products contain. (R 20 (Roy, Dep. at 24)).

413. Roy did not review or obtain any of the products or product labels for the Challenged Products. (R 20 (Roy, Dep. at 7-8)).

414. Roy does not have any formal training in medicine. (R 20 (Roy, Dep. at 26)).

415. Roy has never treated patients, or consulted with healers who were treating particular patients. (R 20 (Roy, Dep. at 28)).

416. Roy and his laboratory have not performed any clinical trials. (R 20 (Roy, Dep. at 13)).

417. Roy has never performed any experiments on humans to measure the efficacy of any medical treatments. (R 20 (Roy, Dep. at 14)).

d. Dews

418. Dews was asked to provide his opinion on 7 Herb Formula. He concluded that all seven herbs are listed in the Herbal Phyicians' [sic] Desk Reference, that there are many references on what these herbs are used for, and that, in manufacturing the formula, he was careful to make sure it was safe. When formulating the product that eventually became 7 Herb Formula, Dews avoided using too much rhubarb, which has a laxative action, because he did not want the product to cause diarrhea. (R 6 (Dews Report) at 1, 8-9).

419. Dews' opinions do not address whether competent and reliable scientific evidence is necessary to substantiate advertising claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 6 (Dews Report)).

420. Dews' opinions do not address whether there is competent and reliable scientific evidence to support advertising claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 6 (Dews Report)).

421. Dews' opinions do not address whether Respondents possessed and relied upon competent and reliable scientific evidence to support Respondents' claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 6 (Dews Report)).

e. Lehr

422. Lehr was asked to opine on the efficacy of DCO products. His opinions are based on his own personal experience in taking the DCO product called PrePost. It was Lehr's opinion that since he started taking the DCO product PrePost, his "life is totally different. . . . It's just incredible. . . . And it's astounding, I mean." (R 21 (Lehr Report) at 6).

423. Lehr's opinions do not address whether competent and reliable scientific evidence is necessary to substantiate advertising claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 21 (Lehr Report)).

424. Lehr's opinions do not address whether there is competent and reliable scientific evidence to support Respondents' advertising claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 21 (Lehr Report)).

425. Lehr's opinions do not address whether Respondents possessed and relied upon competent and reliable scientific evidence to support claims that any of the Challenged Products prevent, treat, or cure cancer, inhibit tumors, and/or heal the destructive effects of radiation and chemotherapy. (R 21 (Lehr Report)).

III. ANALYSIS AND CONCLUSIONS OF LAW

A. Burden of Proof

The parties' burdens of proof are governed by Federal Trade Commission Rule 3.43(a), Section 556(d) of the Administrative Procedure Act ("APA"), and case law. FTC Rules of Practice, Interim rules with request for comments, 66 Fed. Reg. 17,622, 17,626 (Apr. 3, 2001). Pursuant to Commission Rule 3.43(a), "[c]ounsel representing the Commission . . .

shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto." 16 C.F.R. § 3.43(a). Under the APA, "[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 U.S.C. § 556(d).

Respondents contend that, because of the constitutional issues raised by Respondents, Complaint Counsel should be required to prove the elements of the charges against Respondents by "clear, cogent and convincing evidence." RCOL 1; RB at 4 n.2 (citing *Addington v. Texas*, 441 U.S. 418 (1979)). Respondents' argument has no merit. *Addington* addressed the standard of proof required to commit an individual involuntarily to a state mental hospital – a serious deprivation of a well-recognized, constitutionally protected liberty interest. As shown in Section III E *infra*, Respondents' constitutional arguments are unsupported by fact or law. Accordingly, *Addington* does not alter the applicable standard of proof for this case.

It is well established that the preponderance of the evidence standard governs FTC enforcement actions. *In re Telebrands Corp.*, No. 9313, 140 F.T.C. 278, 426, 2004 FTC LEXIS 154, at *76 (Sept. 15, 2004), *aff'd*, 140 F.T.C. 278, 2005 FTC LEXIS 178 (Sept. 19, 2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006); *In re Automotive Breakthrough Sciences, Inc.*, No. 9275, 1998 FTC LEXIS 112, at *37 n.45 (Sept. 9, 1998) (holding that each finding must be "supported by a preponderance of the evidence in the record"); *In re Adventist Health System/West*, No. 9234, 117

F.T.C. 224, 1994 FTC LEXIS 54, at *28 (Apr. 1, 1994) ("[e]ach element of the case must be established by a preponderance of the evidence"); *In re Bristol-Meyers Co.*, No. 8917, 102 F.T.C. 21, 1983 FTC LEXIS 64, at *143 (July 5, 1983) (stating that complaint counsel has "the burden of proving by a preponderance of credible evidence that the challenged advertising claims have not been established or did not have a reasonable basis"), *aff'd*, 738 F.2d 554 (2d Cir. 1984). *See also Steadman v. SEC*, 450 U.S. 91, 102 (1981) (holding that APA establishes preponderance of the evidence standard of proof for formal administrative adjudicatory proceedings).

"[T]he Commission has only such jurisdiction as Congress has conferred upon it by the Federal Trade Commission Act." *Community Blood Bank v. FTC*, 405 F.2d 1011, 1015 (8th Cir. 1969) (citations omitted). When the jurisdiction of the Commission is challenged, the Commission bears the burden of establishing its jurisdiction. *Id.* (citations omitted); *In re College Football Ass'n*, No. 9242, 1994 FTC LEXIS 350, at *7 n.3 (July 21, 1991) (citing *Oliver v. Trunkline Gas Co.*, 789 F.2d 341, 343 (5th Cir. 1986)) ("Complaint [C]ounsel bear the burden of 'affirmatively' establishing that jurisdiction exists."). Jurisdictional facts, like substantive liability, must be established by a preponderance of the evidence. *See McNutt v. General Motors Acceptance Corp.*, 298 U.S. 178, 189 (1936); *FTC v. Warner Chilcott Holdings Co. III*, No. 05-2179, 2007 U.S. Dist. LEXIS 4240, at *17 (D.D.C. Jan. 22, 2007).

The Complaint in this case alleges that Respondents did not possess and rely upon a reasonable basis that substantiated the representations Respondents made in the challenged advertisements. Complaint ¶ 16. Complaint Counsel has the burden of proving by a preponderance of credible evidence that Respondents made the claims in the challenged advertising and did not have a reasonable basis for such claims. *In re Bristol-Myers Co.*, 1983 FTC LEXIS 64, at *143. *See FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 959 (N.D. Ill. 2006) (holding that to prevail on a reasonable basis theory, the FTC must prove that the advertiser lacked a reasonable basis for asserting the challenged claim, that the advertiser has the burden of establishing the substantiation it relied on for its claim, and that the FTC has the burden of proving that the advertiser's substantiation is inadequate), *aff'd*, 512 F.3d 858 (7th Cir. 2008).

B. Jurisdiction over Respondents

1. Positions of the parties and procedural background

Respondents assert that DCO is a not-for-profit religious organization and, as such, is not subject to the jurisdiction of the FTC. R Juris. Br. at 1-2. Specifically, Respondents assert that DCO is a religious ministry, incorporated as a corporation sole under the nonprofit corporation statutes of the State of Washington, and that James Feijo is the overseer of DCO, as defined under the corporation sole statute. R Juris.

Br. at 1. Respondents further state that, as part of its missionary work, DCO addresses the health concerns of its followers, which led DCO to develop the Challenged Products. R Juris. Br. at 2. Maintaining that its religious ministry is not organized to carry on business for its own profit or that of its members, Respondents argue that DCO is not a corporation, as is required for jurisdiction under Sections 4 and 5 of the FTC Act. R Juris. Br. at 7-8.

Complaint Counsel argues that DCO is not a bona fide charitable institution, but is instead a for-profit commercial enterprise, completely controlled by James Feijo, from which he and his family derive substantial pecuniary benefits. CC Juris. Br. at 4. Complaint Counsel further contends that Feijo runs a multi-million dollar commercial operation that competes with for-profit entities in commerce. CC Juris. Br. at 5.

On April 21, 2009, a hearing was held for the limited purpose of determining whether DCO is a corporation within the meaning of Section 4 of the FTC Act, 15 U.S.C. § 44, and applicable case law. Apr. 21, 2009 Hearing on Jurisdiction ("HOJ"). After the conclusion of that hearing, a ruling was issued from the bench that Complaint Counsel had demonstrated, by a preponderance of the evidence, that there is jurisdiction over both Respondents, DCO and James Feijo, under Sections 4 and 5 of the FTC Act, 15 U.S.C. §§ 44 and 45, and that the conduct challenged in this case is in or affecting commerce within the meaning of those Sections. HOJ Tr. 347-48. *See also*

Order Memorializing Bench Rulings on Jurisdiction, Respondents' Motion to Dismiss, Motions for Summary Decision, and Respondents' Motion for Stay Pending Interlocutory Appeal, Apr. 27, 2009. The analysis in support of that ruling follows.

2. Summary of background facts

Respondents maintain that DCO is a house church. According to James Feijo, a house church is a church operating not in the typical sense, with a building, sign, and established doctrines, but instead is a church meeting in houses to worship and break bread, with no set times for religious meetings. (J. Feijo, HOJ Tr. 180-82, 263-64). James and Patricia Feijo testified that DCO was created for the purpose of healing based on the scripture of Daniel Chapter One and other Biblical verses, including Genesis 1:29 where it is written that God said he created all things for our food for healing. (J. Feijo, Tr. 417-23; R 16 (P. Feijo, Dep. at 39-40)). According to Patricia Feijo, the name Daniel Chapter One comes from the Book of Daniel in the Old Testament of the Bible, in which Daniel and his men were in captivity and were expected to eat the king's very rich diet of meats and wine, but instead ate and drank only pulse and water; after 10 days, their eyes were said to be brighter and they were said to be stronger than the king's men. (R 16 (P. Feijo, Dep. at 40-41)).

James and Patricia Feijo testified that DCO's ministry activities include helping house churches in

other countries, holding religious meetings, performing baptisms, delivering babies, performing marriage ceremonies, performing healings, and reaching out to others to inform them about Respondents' perspectives on the integration of spiritual and physical well-being. (R 16 (P. Feijo, Dep. at 204-05); J. Feijo, HOJ Tr. 99, 180-83, 236-37; R 15 (J. Feijo, Dep. at 73); P. Feijo, Tr. 325-26). Respondents claim that they have created a combined spiritual and scientific approach that maintains the balance of bodily systems. F. 85. James Feijo named this approach "BioMolecular Nutrition." F. 85.

Respondents sell the four products challenged in the Complaint over the Internet through their websites and through the BioMolecular Nutrition Product Catalog, which lists and describes products sold by DCO. F. 84, 91. The BioMolecular Nutrition Product Catalog sets forth the DCO Website address, www.danielchapterone.com, for consumers to shop online, and lists the toll-free number that consumers can use to place orders. F. 91. In addition, Respondents operate a radio program, DCO HealthWatch, to which cancer patients have called in and received counseling about taking the Challenged Products. F. 108-10. Respondents contend that because their activities in promoting and selling the DCO Products are in furtherance of the Feijos' spiritual and scientific beliefs, they are outside the FTC's jurisdiction.

3. Analytical framework

In analyzing whether the FTC has jurisdiction over Respondents, the starting point is the language of the statute itself. *United States v. Turkette*, 452 U.S. 576, 580 (1981). Section 5(a)(1)-(2) of the FTC Act grants the FTC the authority to "prevent unfair or deceptive acts or practices in or affecting commerce" by "persons, partnerships, or corporations." 15 U.S.C. § 45(a)(1)-(2). Section 4 of the FTC Act defines "corporation" in part as "any company, trust, so-called Massachusetts trust, or association, incorporated or unincorporated, . . . without shares of capital or capital stock or certificates of interest, except partnerships, which is organized to carry on business for its own profit or that of its members." 15 U.S.C. § 44.

In interpreting the language of Section 4 of the FTC Act, courts and the Commission have consistently held that an entity organized as a nonprofit is within the jurisdiction of the FTC if the entity in fact engages in business for its own profit or that of its members. *California Dental Ass'n v. FTC*, 526 U.S. 756, 766-67 (1999); *Community Blood Bank*, 405 F.2d at 1017 (Commission's jurisdiction extends to any legal entity without shares of capital which engages in business for profit in the traditional meaning of that language). In *Community Blood Bank*, the Court of Appeals explained that "under § 4 the Commission lacks jurisdiction over nonprofit corporations without shares of capital, which are organized for and actually engaged in business for only charitable purposes, and do not derive any 'profit' for themselves or their

members within the meaning of the word 'profit' as attributed to corporations having shares of capital." 405 F.2d at 1022. Commenting on *Community Blood Bank*, the Commission stated: "The court thus established a two-pronged test looking both to the source of the [entity's] income, i.e., to whether the corporation is 'organized for and actually engaged in business for only charitable purposes,' and to the destination of the income, i.e., to whether either the corporation or its members derive a profit." *In re College Football Ass'n*, 1994 FTC LEXIS 350, at *51-52.

Thus, the analysis of jurisdiction in this case begins with an evaluation of the source of DCO's income and an inquiry into whether DCO is actually engaged in business only for charitable purposes. Then, the focus turns to whether DCO in fact engages in business for its own profit or that of its members. In addition, jurisdiction over James Feijo individually is assessed. Finally, the evidence that Respondents' activities are in or affecting commerce is evaluated to establish that the FTC has jurisdiction over Respondents with respect to the acts or practices challenged in the Complaint.

4. DCO is not a business organized or engaged in only charitable purposes

a. DCO operates a commercial enterprise

Profit, the "jurisdictional touchstone" of the FTC Act, *California Dental*, 526 U.S. at 767, is determined

in accordance with the "traditional and generally accepted meaning of that word." *Community Blood Bank*, 405 F.2d at 1017. "According to a generally accepted definition 'profit' means gain from business or investment over and above expenditures, or gain made on business or investment when both receipts or payments are taken into account." *Community Blood Bank*, 405 F.2d at 1017. The dictionary definition of profit includes "a valuable return: GAIN," and "to be of service or advantage . . . to derive a benefit: GAIN," as well as the traditional concept of profit in business as "the excess of returns over expenditure in a transaction or series of transactions; esp[ecially] the excess of the selling price of goods over their cost." *Merriam-Webster's Collegiate Dictionary* (10th ed. 1993).

Respondent DCO has a toll-free phone number and a call center and operates websites through which consumers may purchase DCO products. F. 84, 99, 103-04. In addition, DCO sells its products through stores in Georgia and Pennsylvania and through various distributors, including chiropractic centers. F. 116-19. The DCO Website contains a tab inviting consumers to shop at DCO's "On-Line Store." F. 105. The "About Us" section on the DCO Website describes the company as a "health food store" or "health food supplement store." F. 32. In their websites and brochures, Respondents compare their products and their organization to "other brands" or "other companies." *E.g.*, F. 137; F. 138 (DCO Website

stating: "Daniel Chapter One is the first and only company to add Siberian ginseng to the formula").

Over a thousand consumers have purchased DCO's products. F. 81. Respondents have generated approximately $2 million in annual sales for the years 2006, 2007, and 2008 for all of DCO's nearly 200 products. F. 9. Its sales of the Challenged Products constitute twenty or thirty percent of its sales. F. 80. Respondents charge consumers three to ten times what it costs Respondents to purchase the Challenged Products from manufacturers. F. 83, 127-29, 140-42, 144-46.

Significantly, DCO was incorporated as a for-profit corporation from 1991 to 1997 and sold the Challenged Products since at least 1993 and throughout the 1990s. F. 12-13, 22-23, 27. DCO's Articles of Incorporation during this period stated that the purpose for which DCO was organized as a for-profit corporation was: "To engage in the sale, retail, wholesale and distribution of health products, including but not limited to health foods and supplements, namely those with special nutritive qualities and values." F. 23. DCO changed its corporate form to corporation sole in 2002 and continued to sell the Challenged Products. F. 8-9, 28.

It appears that DCO's revenues exceed its expenses, since DCO was able to completely support two individuals and their homes (*see infra* Section III B 5) and to maintain surpluses in various accounts in the hundreds of thousands of dollars for extended

periods of time.[2] F. 42-45. A showing that DCO was successful in running its business, however, is not required. *See California Dental*, 526 U.S. at 768 n.6 ("It should go without saying that the FTC Act does not require for Commission jurisdiction that members of an entity turn a profit on their membership, but only that the entity be organized to carry on business for members' profit."); *In re Ohio Christian College*, No. 8820, 80 F.T.C. 815, 849-50, 1972 FTC LEXIS 223, at *72 (May 19, 1972) (stating that the fact that respondents "were apparently not very successful in their enterprise" was of "little consequence").

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[2] The record on DCO's revenues and expenditures is not clear. It is noted that Respondents failed to fully comply with discovery requests regarding their finances, even after being ordered to do so, but Complaint Counsel was able to obtain some limited financial records by subpoena. Complaint Counsel asked for an adverse inference that the information sought from Respondents in discovery would have defeated Respondents' nonprofit argument. CC Juris. Br. at 22. James Feijo, DCO's sole trustee, testified that he does not keep records or keep track of the money DCO distributes. F. 6, 40, 47; *see also* F. 50-54 (Respondents did not maintain documents even after being ordered to produce documents in this proceeding). Although an adverse inference in this case may have been appropriate, *see Hamilton v. Accu-Tex*, 32 F. Supp. 2d 47, 68 (E.D.N.Y. 1998) (drawing adverse inference on interstate revenue in order to determine interstate commerce, an element for long-arm jurisdiction, and finding "since the necessary information is in the exclusive control of defendants, where they have failed to provide the information, this Court finds that plaintiffs have satisfied their burden, and the case should proceed"), it is not necessary here, because the facts are sufficient to demonstrate that DCO operated as a business for its own profit or that of its members.

b. DCO is not organized only for charitable purposes

Respondents' principal ground for arguing that the FTC lacks jurisdiction is that DCO is a ministry, organized as a corporation sole under the laws of the State of Washington as of October 30, 2002, and that James Feijo is the overseer of Daniel Chapter One, within the meaning of the Washington State statute authorizing the creation of a corporation sole. R Juris. Br. at 1 (citing R 1 (DCO's Articles of Incorporation) and Rev. Code Wash. (ARCW) § 24.12.030). However, courts and the Commission look to the substance, rather than the form, of incorporation in determining jurisdiction under the FTC Act. *Community Blood Bank*, 405 F.2d at 1019 ("mere form of incorporation does not put [an entity] outside the jurisdiction of the Commission"); *In re American Medical Ass'n*, No. 9064, 94 F.T.C. 701, 1979 FTC LEXIS 182, at *239 (Oct. 12, 1979), *enforced as modified*, 638 F.2d 443 (2d Cir. 1980), *aff'd by an equally divided court*, 455 U.S. 676 (1982). Regardless of DCO's form of incorporation, the evidence shows that DCO bears none of the substantive indicia of a corporation that is truly organized only for charitable purposes.

DCO is not registered with the Internal Revenue Service as a tax-exempt organization under Section 501(c)(3) or any other section of the IRS Code. F. 31. In evaluating the FTC's jurisdiction, "[t]he Commission has long recognized that while the terms employed in other statutes and the interpretation adopted by other agencies are not controlling, the

treatment of exemptions for nonprofit corporations by other branches of the Federal Government is helpful." *In re College Football Ass'n*, 1994 FTC LEXIS 350, at *52 (June 16, 1994) (citing *In re Ohio Christian College*, 80 F.T.C. at 848; *In re American Medical Ass'n*, 1979 FTC LEXIS 182, at *254 (finding an entity's tax-exempt status certainly one factor to be considered and observing that a determination by another federal agency that a respondent is or is not organized and operated exclusively for eleemosynary purposes should not be disregarded)). In *Community Blood Bank*, the fact that respondents were exempt from federal income tax liability was among the factors weighed in finding that the FTC lacked jurisdiction. 405 F.2d at 1020.

Respondents contend that it is immaterial for jurisdictional purposes that DCO does not have a Section 501(c)(3) tax exemption because, according to Respondents, churches do not need to obtain such exemption, pursuant to Section 508(c)(1)(A) of the IRS Code. Contrary to Respondents' argument, Section 508(c)(1)(A) exempts churches from certain notice requirements applicable to other entities seeking to obtain a Section 501(c)(3) tax exemption, and has no bearing on the issue of FTC jurisdiction.[3]

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[3] Section 508 provides in pertinent part:

(a) . . . Except as provided in subsection (c), an organization organized after October 9, 1969, shall not be treated as an organization described in section 501(c)(3) [26 USCS § 501(c)(3)] –

(Continued on following page)

Moreover, as summarized below, in Section III B 5, DCO distributes funds for the use of both James and Patricia Feijo, private individuals and DCO's corporate officers. The Internal Revenue Code provides an exemption from income taxation for corporations where "no part of the net earnings of which inures to the benefit of any private . . . individual." 26 U.S.C. § 501(c)(3). The Nonprofit Corporation Act of the State of Washington defines a nonprofit corporation as a corporation no part of the income of which is distributable to its members, directors, or officers.

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(1) unless it has given notice to the Secretary, in such manner as the Secretary may by regulations prescribe, that it is applying for recognition of such status, or

(2) for any period before the giving of such notice, if such notice is given after the time prescribed by the Secretary by regulations for giving notice under this subsection.

(b) Presumption that organizations are private foundations. Except as provided in subsection (c), any organization (including an organization in existence on October 9, 1969) which is described in section 501(c)(3) [26 USCS § 501(c)(3)] and which does not notify the Secretary, at such time and in such manner as the Secretary may by regulations prescribe, that it is not a private foundation shall be presumed to be a private foundation.

(c) Exceptions.

(1) Mandatory exceptions. Subsections (a) and (b) shall not apply to –

(A) *churches*, their integrated auxiliaries, and conventions or associations of churches. . . .

(emphasis added).

Rev. Code Wash. (ARCW) § 24.03.005. With the distribution of funds for use by James and Patricia Feijo, DCO would not qualify as a tax-exempt nonprofit corporation under either the Internal Revenue Code or laws of the State of Washington.

In addition, DCO's Articles of Incorporation do not declare that DCO was organized exclusively for charitable or other clearly nonprofit purposes, but instead include provisions permitting "other worthwhile projects for the common good of Daniel Chapter One and its close associates, along with other acts and programs beneficial to Daniel Chapter One at large." F. 29-30. Further, DCO's Articles of Incorporation do not provide for distribution of its assets upon dissolution solely to other nonprofit entities or prohibit distribution of its earnings to the benefit of any individual or for-profit corporation. F. 30. By contrast, in *Community Blood Bank*, in which the Court found the FTC lacked jurisdiction, the articles of incorporation of the nonprofit entities: declared that they were organized exclusively for educational and charitable purposes; declared that no part of their earnings shall inure to the benefit of any member or any other individual or corporation; and, required that the corporation's assets, upon dissolution, be disposed of in accordance with the provisions of the state's nonprofit corporation law. 405 F.2d at 1020.

c. DCO is not engaged in business only for charitable purposes

It is not disputed that DCO has engaged in some charitable activities. In some instances, Respondents gave away DCO products and provided counsel to persons in need. F. 19, 21. Respondents have at times allowed people in need to stay in their house and provided support to a junior men's fast-pitch softball team. F. 19-20. However, Respondents did not provide documents to indicate how much of DCO's products they have given away or how much financial support they have dedicated to charitable activities, and the testimony on this point was inconclusive. F. 54. Furthermore, the evidence shows, as summarized in Section III B 5 *infra*, that in addition to its charitable activities, DCO distributes funds to support all of the living expenses of both James and Patricia Feijo. This contribution of funds to the Feijos defeats Respondents' claim that DCO is operated exclusively for charitable purposes. As noted in *Community Blood Bank*: "A religious association might sell cookies at a church bazaar, or receive income from securities it holds, but so long as its income is devoted exclusively to the purposes of the corporation, and not distributed to members or shareholders, it surely does not cease to be a nonprofit corporation merely because it has income. . . ." *Community Blood Bank*, 405 F.2d at 1019-20 (quoting with approval dissenting opinion in *In re Community Blood Bank*, 70 F.T.C. 728, 1966 FTC LEXIS 30, at *455 (Sept. 28, 1968)). In *Community Blood Bank*, the uncontradicted evidence showed

that no part of any funds received by respondents had ever been distributed to or inured to the benefit of any of their members, directors, or officers. *Community Blood Bank*, 405 F.2d at 1020. But here, as summarized below, where the evidence clearly shows that DCO distributes funds to the Feijos, DCO's income is not devoted exclusively to charitable or other nonprofit purposes.

5. DCO engages in business for its own profit or that of its members

Whether Respondent DCO is a ministry is not dispositive in determining the FTC's jurisdiction over Respondents' activities. Instead, the pivotal inquiry is whether Respondent DCO engaged in business for its own profit or that of its members. *California Dental*, 526 U.S. at 766-67; *Community Blood Bank*, 405 F.2d at 1017. In *Community Blood Bank*, the individual respondents "were 'public-spirited volunteers' and derived no personal profit, benefit or advantages in their individual occupations . . . from their participation in the activities of the community-wide blood bank program." 405 F.2d at 1021. "Their activities at all times were directed toward promoting a community-sponsored program in the public interest and at no time were infected with commercial intent." *Id.* at 1021-22. The Commission, in *Ohio Christian College*, noted that the court in *Community Blood Bank* found that the challenged boycotting activities were motivated by a sincere belief that commercial trafficking in blood was immoral and not in the public interest.

In re Ohio Christian College, 1972 FTC LEXIS 223, at *65. The Commission went on to state: "Whether one agrees with this belief or not, it is apparent the actions of the corporate respondents in *Community Blood Bank* were well-intentioned and did not inure to the financial benefit of anyone." *Id.*

Thus, the Commission has made clear that, for finding jurisdiction, what matters is not what respondents' subjective motivations are, but whether respondents' actions inure to their own financial benefit. Applying that principle to this case, what matters, for finding jurisdiction, is not whether Respondents' commercial activities are motivated by religious beliefs, but whether Respondents' activities inured to their own financial benefit, which, as summarized below, they clearly did.

a. DCO distributes funds to the Feijos

"[T]he distribution of funds to private persons or for-profit companies as opposed to their use for 'recognized public purposes' is one basis for finding an entity to be 'organized to carry on business for . . . profit.'" *In re College Football Ass'n*, 1994 FTC LEXIS 350, at *49. *See also California Dental*, 526 U.S. at 766-67 (holding that jurisdiction arose from economic and pecuniary benefits conferred by nonprofit trade association on its for-profit members); *In re American Medical Ass'n*, 1979 FTC LEXIS 182, at *240 (stating that Section 4 does not require a transfer or delivery

of monetary profits to the members of a non-stock corporation, but only pecuniary benefits to its members from the corporation's activities); *In re Ohio Christian College*, 1972 FTC LEXIS 223, at *68 ("'Profit does not necessarily mean a direct return by way of dividends, interest, capital account or salaries. A saving of expense which would otherwise necessarily be incurred is also a profit to the person benefitted.'") (citation omitted).

It is undisputed that DCO pays all of the Feijos' living expenses. F. 58. DCO or its affiliate owns two houses (one in Rhode Island and one in Florida, on country club land with a pool in the back), in which the Feijos stay without paying rent. F. 55. DCO also owns two cars (a 2003 Cadillac and a 2004 Cadillac) which the Feijos use. F. 56-57. Respondent James Feijo does not have his own individual bank account. F. 76. Both James and Patricia freely use DCO credit cards for personal expenses. F. 66. DCO pays all of the Feijos' expenses, including pool and gardening services for the Feijo house in Florida; Patricia Feijo's tennis club membership; James Feijo's membership at the Green Valley Country Club in Rhode Island; and, during the period from December 2005 to March 2009, golf expenses of $9,936, restaurant expenses of $14,024, automobile expenses of $28,582, and cigar expenses of $1,077. F. 58, 61-70. This distribution of funds, which amounts to a saving of expense which might otherwise be incurred by the Feijos, is a profit to the Feijos and provides a basis for finding that DCO is organized to carry on business for profit.

Respondents argue that jurisdiction should not be based upon the economic benefits conferred upon the Feijos because the Feijos do not take salaries from DCO for their work and because they live modestly. R Juris. Br. at 7. Neither of these things affects jurisdiction in this case. The Feijos have no need to take salaries, since James Feijo controls all of the assets of DCO and can direct whatever funds he chooses for the support of himself and his wife. F. 6, 40. Second, it is not necessary for the Feijos to live lavishly for jurisdiction to be proper under Section 4. The Supreme Court, in *California Dental*, specifically rejected the notion that the profit received must be substantial: "There is accordingly no apparent reason to let the statute's application turn on meeting some threshold percentage of activity for this purpose [of profit], or even satisfying a softer formulation calling for a substantial part of the nonprofit entity's total activities to be aimed at its members' pecuniary benefit. To be sure, proximate relation to lucre must appear. . . ." 526 U.S. at 766. It is sufficient for the purpose of finding jurisdiction that the economic benefits conferred are more than "*de minimis*" or "merely presumed." *Id.* at 767 and 767 n.6. In this case, the complete financial support of James and Patricia Feijo, including, among other things, two homes, two cars, tennis lessons, rounds of golf, cigars, restaurant meals, and club memberships, constitutes neither simply presumed nor *de minimis* economic benefits.

The Commission found jurisdiction under Section 4 on similar facts in *Ohio Christian College*, which involved deceptive trade practices by a nonprofit religious college. The Commission stated:

> [T]he question is not whether a corporation amassed profit, but how it disposed of such profit. From the facts available to the Commission, we find the relationship between [Ohio Christian College] and the individual respondents in dealing with the dissipation of profits strikingly similar to that existing between a closely-held commercial corporation and its officer-shareholders. The cavalier treatment of the corporate assets and finances leads us to conclude that respondents considered them their own. The individual respondent . . . has complete control over the purse strings, he sets all salaries (including his own), determines all allocation and expenditures, signs all checks and exercises plenary power over the affairs of the school. The record shows the corporation was organized and controlled so that the individual respondents could take what they wanted prior to any further disposition or comingling of funds.

1972 FTC LEXIS 223, at *69-70.

In this case, as well, James Feijo treated the income and expenditures of DCO cavalierly. He claimed to keep no financial records, and to have no idea of how much money DCO had or how much money was spent on various aspects of its operations or for the

support of the Feijos' living expenses. F. 47, 50, 59. Moreover, since James Feijo had no individual bank account, he used DCO's assets at will, thereby treating those assets as his own. As in *Ohio Christian College*, such circumstances support jurisdiction over DCO as an entity that is organized to carry on business for profit.

b. DCO's profit inures to its sole member, James Feijo

As a corporation sole, DCO has one member, James Feijo, the overseer of DCO. Pursuant to the State of Washington's Nonprofit Corporation Act, under which DCO is organized:

> Any person, being the . . . overseer . . . of any church or religious denomination in this state, may, in conformity with the constitution, canons, rules, regulations or discipline of such church or denomination, become a corporation sole, in the manner prescribed in this chapter . . . ; and, thereupon, said . . . overseer . . . shall be held and deemed to be a body corporate, with all the rights and powers prescribed in the case of corporations aggregate; and with all the privileges provided by law for religious corporations.

Rev. Code Wash. (ARCW) § 24.12.010. *See also Barnett v. Hicks*, 792 P.2d 150, 155 (Wash. 1990) (Dore, J., dissenting on other grounds) (noting that under Washington law, a corporation sole vests full management power in one individual).

The evidence in this case shows that James Feijo controls the money made by DCO. F. 6, 40-41. The structure of the corporation sole enables James Feijo to set his and his wife's salaries and benefits without the check of a managing board of directors or other individuals. Further, DCO pays all of the Feijos' living expenses, including food, clothing, housing, transportation, travel, recreation, and more. F. 55-58, 61-70. These economic benefits constitute profit to James Feijo. Thus, DCO engages in business for the profit of its sole member, James Feijo.

6. James Feijo is a person over whom the FTC has jurisdiction

The FTC has jurisdiction under Section 5(a)(2) over persons, partnerships or corporations. 15 U.S.C. § 45(a)(2). If individuals direct and control the acts and practices of a corporation amenable to the FTC's jurisdiction, then they too may be made subject to the FTC's jurisdiction. *In re Ohio Christian College*, 1972 FTC LEXIS 223, at *62-63; *see FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 573 (7th Cir. 1989) (holding that individual who either participated directly in or had the authority to control deceptive acts or practices may be held liable under the FTC Act for the violations of his corporation).

Respondent James Feijo both participated directly in and had the authority to control the acts or practices challenged in this case. Respondents admit that Respondent Feijo is responsible for the activities

of Respondent DCO as its overseer. F. 5. The activities for which he is responsible include the development, creation, production, and distribution of the Challenged Products; the creation, management, and maintenance of DCO's toll-free telephone number through which consumers may order the Challenged Products; the setting of prices for the Challenged Products; and the creation, drafting, and approval of the directions for usage and the recommended dosages of the Challenged Products. F. 37-39, 100. Respondent James Feijo and his wife, Patricia Feijo, are also responsible for the information contained in DCO's advertising and promotional materials, including the BioGuide, the Cancer Newsletter, the Most Simple Guide, and the websites www.danielchapterone.com, www.7herbformula.com, and www.gdu2000.com. F. 165-66, 173, 178. In addition, Respondent Feijo and his wife co-host the DCO radio program, Daniel Chapter One HealthWatch, for two hours daily, Monday through Friday, on which they have counseled individuals who have called into the radio program about taking DCO's products. F. 108-10, 178. Finally, Respondent Feijo is the trustee for all of DCO's assets, including all funds which are held in trust. F. 6, 40. Thus, Respondent James Feijo had the authority to direct and control, in fact did direct and control, and participated directly in the challenged acts or practices of DCO, a corporation that is subject to the FTC's jurisdiction. Accordingly, Respondent James Feijo is a person over whom the Commission has jurisdiction, and he may be held individually

liable under the FTC Act for the deceptive acts and practices found below.

7. Respondents engage in interstate commerce

Section 5(a)(1) of the FTC Act declares unlawful "unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45(a)(1). Section 12 of the FTC Act provides that the dissemination of any false advertisement, for the purpose of inducing the purchase in or having an effect upon commerce, of food or drugs, shall be an unfair or deceptive act or practice in or affecting commerce within the meaning of Section 5. 15 U.S.C. § 52.

In their Answer, Respondents admit that they distribute the Challenged Products in commerce. Answer ¶ 4. Respondent DCO operates a call center and websites through which consumers may purchase the Challenged Products. F. 99, 103-04. DCO has sold its products nationally through a number of stores, distributors, and chiropractic centers, including those in Florida, Georgia, Missouri, and Pennsylvania. F. 116-17, 119. These sales are in or affecting commerce. *See United States v. Robertson*, 514 U.S. 669, 672 (1995) ("[A] corporation is generally engaged in commerce when it is itself directly engaged in the production, distribution, or acquisition of goods or services in interstate commerce.") (per curiam) (citation omitted). In addition, Respondents' advertisements of its products through the DCO websites

(F. 158-61), which reach a national audience invoke the FTC's jurisdiction. *See FTC v. Simeon Management Corp.*, 391 F. Supp. 697, 703 (N.D. Cal. 1975) (holding that advertisements placed in newspapers, magazines, and on television with out-of-state circulations and broadcasting ranges, were sufficiently involved in or affecting commerce to invoke the FTC's jurisdiction).

To the extent that Respondents maintain that they do not sell the Challenged Products, but instead offer them for suggested donations, the evidence is to the contrary. For example, on their website www.dc1store.com, Respondents state: "For Information on Special offers for purchasing multiple bottles of 7-Herb call 1-800-504-5511 between 9-6 EST Mon-Fri." F. 107. In the BioMolecular Nutrition Product Catalog, which lists and describes the Challenged Products and states "Call Toll free or shop online," there is no indication that the listed prices are suggested donations. F. 91-92.

An FTC investigator purchased the Challenged Products from the DCO Website, www.danielchapterone.com, on January 3, 2008. F. 147. At the time of his purchase, each of the Challenged Products was displayed on the DCO Website with a picture of the product, a short description of the product, and a corresponding price. F. 148. The shipment to the investigator of the Challenged Products did not contain any documents indicating that the purchase was a donation or thanking the purchaser for making a donation to DCO. F. 156. An e-mail the FTC investigator

received after his purchase of the Challenged Products stated: "Thank you for your purchase on our online store. . . . We appreciate your business with us," and offered a ten percent discount on a subsequent purchase. F. 152.

The evidence clearly demonstrates that Respondents advertise and sell products, including the Challenged Products, throughout the United States, and that their sales are in or affecting commerce. Thus, the Commission has jurisdiction over Respondents, and the conduct challenged in the Complaint, pursuant to Sections 4 and 5 of the FTC Act, 15 U.S.C. §§ 44, 45.

8. Summary of jurisdiction

The FTC has jurisdiction over DCO as a corporation, within the meaning of Section 4 of the FTC Act. Jurisdiction is also proper as to James Feijo, as a person directly participating in and controlling all activity of DCO, under Section 5 of the FTC Act. The conduct of Respondents is in or affecting commerce, pursuant to Sections 5 and 12 of the FTC Act. Accordingly, the FTC has jurisdiction in this matter.

C. Respondents' Dissemination of Advertisements to Induce Purchases of Food or Drugs

Section 12 of the FTC Act makes it unlawful "for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false

advertisement . . . [b]y any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce of food, drugs, devices, services, or cosmetics." 15 U.S.C. § 52. Prior to addressing whether the DCO materials are false, within the meaning of Section 12, it must be determined preliminarily whether the materials constitute: (1) the dissemination of advertisements; (2) for the purpose of inducing, or which are likely to induce, purchases in or affecting commerce; (3) of "food" or "drugs."

1. Materials disseminated about the Challenged Products constitute advertisements

"Advertisement" is not defined in the FTC Act. The ordinary meaning of the word is: The act or process of calling something to the attention of the public; or a public notice, especially one published in the press or broadcast over the air. *Merriam-Webster's Collegiate Dictionary* (10th ed. 1993). Black's Law Dictionary defines "advertisement" as a "[n]otice given in a manner designed to attract public attention. Information communicated to the public, or to an individual concerned. . . ." *Black's Law Dictionary* 54 (6th ed. 1990) (citation omitted). *See also B & B Coastal Enters., Inc. v. Demers*, 276 F. Supp. 2d 155, 159 n.3 (D. Me. 2003) (noting that local ordinance regulating advertising signs applied to any sign which "directs attention to the type of business or profession conducted, as well as to a commodity or

service, sold, offered, or manufactured . . . "). As discussed below, the evidence amply demonstrates that the DCO materials at issue in this case constitute the dissemination of "advertisements" for purposes of Section 12.

First, information about the Challenged Products is disseminated to the public, over the Internet, through the websites www.danielchapterone.com, www.7herb formula.com, www.gdu2000.com, www.dc1pages.com, and www.dc1store.com. F. 158, 161. Consumers can locate the DCO Website by entering the term "cancer" in a Google search. F. 162. In addition, information about the Challenged Products is disseminated to the public through printed materials, also available on the DCO Website, including the BioGuide, the Cancer Newsletter, and "The Most Simple Guide." F. 163-64, 169-70, 172. Information about the Challenged Products is also disseminated to the public through BioMolecular Nutrition Product Catalog, F. 91, 154. Finally, information about the Challenged Products is disseminated to the public, via the Monday through Friday, two hour radio program, "Daniel Chapter One HealthWatch." F. 175-77.

The information provided through these media promotes the Challenged Products. Respondent Feijo admits that DCO advertises on the DCO Website. F. 161. DCO's printed materials also promote the attributes of the Challenged Products. For example, the "Most Simple Guide" describes the Challenged Products as "essential for cancer." F. 192. The DCO websites, the BioGuide, and the Cancer Newsletter

promote the products through product descriptions and testimonials. F. 179-80, 183-88, 190, 195, 197-201, 203-10. The BioMolecular Nutrition Product Catalog also describes and promotes the characteristics of the Challenged Products. F. 91, 233, 256, 279. Finally, the radio program uses "health advice" to promote the products. F. 213-17. Accordingly, the DCO materials constitute "advertisements" within the scope of Section 12 of the FTC Act, 15 U.S.C. § 52.

2. The advertisements are for the purpose of inducing, and did induce, purchases of the Challenged Products in or affecting commerce

As noted in Section III B 7 above, Respondents' contention that their products are offered for suggested donations and not for purchase is contrary to the evidence. The DCO Website contains icons inviting consumers to "Buy Now." For example, the DCO Website touts the purported benefits of BioShark immediately adjacent to a link urging the viewer to "BUY NOW!" F. 106, 221. The BioGuide, Cancer Newsletter, and "Most Simple Guide" all prominently feature DCO's toll-free call center number. F. 90, 94, 163, 167, 174. Consumers are also given the toll-free call center number on the DCO radio program. F. 102, 111. In addition, DCO has spent money on advertising its products. F. 159-60. In these circumstances, it is clear that Respondents' advertisements are "intended to" induce sales. Moreover, there is no question that DCO in fact made sales, F. 9, 80-81, and

that its sales are "in or affecting commerce." *See* F. 218; *supra* Section III B 7.

3. The Challenged Products are food and/or drugs

"Food" and "drug," for the purposes of Section 12, are defined in the FTC Act as follows:

> (b) Food. The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.
>
> (c) Drug. The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

15 U.S.C. § 55(b), (c).

Courts and the Commission have routinely treated dietary supplements as within the scope of Section 12. *See FTC v. National Urological Group, Inc.*, No. 1:04-CV-3294, 2008 U.S. Dist. LEXIS 44145

(N.D. Ga. June 4, 2008); *FTC v. Direct Marketing Concepts, Inc.*, 569 F. Supp. 2d 285, 297 (D. Mass. 2008); *FTC v. Garvey*, 383 F.3d 891 (9th Cir. 2004); *Shafe v. FTC*, 256 F.2d 661, 663 (6th Cir. 1958). There is no dispute that the Challenged Products are dietary supplements. RFF 11; Answer ¶¶ 6, 8, 10, 12. In accordance with the foregoing authorities, such articles constitute "food" and/or "drug[s]" within the scope of Section 12. *See In re General Nutrition, Inc.*, No. 9175, 113 F.T.C. 146, 1986 FTC LEXIS 74, at *4 (Feb. 24, 1986) (finding that, as advertised, dietary supplement tablets, "Healthy Greens," constituted a "food" and "drug" within the meaning of Section 12 of the FTC Act).

D. Respondents' Advertising Is Deceptive or Misleading

An "advertisement is deceptive under the Act if it is likely to mislead consumers, acting reasonably under the circumstances, in a material respect." *Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992) (citing *In re Thompson Medical Co.*, No. 9149, 104 F.T.C 648, 788, 1984 FTC LEXIS 6, at *311 (Nov. 23, 1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986); *In re Cliffdale Assocs.*, No. 9156, 103 F.T.C. 110, 164-66, 1984 FTC LEXIS 71, at *104 (Mar. 23, 1984)). *See also* 15 U.S.C. § 55(a)(1) (defining "false advertisement" as an advertisement "which is misleading in a material respect"). Proof of intent to deceive is not required, and "the subjective good faith of the advertiser is not a valid defense." *FTC v. Sabal*, 32 F. Supp. 2d 1004,

1007 (N.D. Ill. 1998); *FTC v. World Travel Vacation Brokers, Inc.*, 861 F.2d 1020, 1029 (7th Cir. 1988).

In determining whether advertising is deceptive, the Commission engages in a three-part inquiry to determine: (1) whether the advertisements convey the claims alleged; (2) whether the claims are false or misleading; and (3) whether the claims are material to prospective consumers. *Kraft v. FTC*, 970 F.2d at 314; *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1095 (9th Cir. 1994); *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 297. Applying that three-part inquiry to this case, it is clear that Respondents' advertising is deceptive.

1. The DCO advertisements make the claims alleged in the Complaint

The Complaint alleges that Respondents disseminated advertisements which claim that the Challenged Products prevent, treat, or cure cancer. Complaint ¶¶ 5, 7, 9, 11, 13. The Complaint further charges that Respondents' advertisements represent that:

> Bio*Shark inhibits tumor growth;
> Bio*Shark is effective in the treatment of cancer;
> 7 Herb Formula is effective in the treatment or cure of cancer;
> 7 Herb Formula inhibits tumor formation;
> GDU eliminates tumors;
> GDU is effective in the treatment of cancer;

> BioMixx is effective in the treatment of cancer; and
> BioMixx heals the destructive effects of radiation and chemotherapy.

Complaint ¶ 14.

Respondents contend that DCO's advertising does not use the words "diagnose, mitigate, cure or prevent," that their "express statements" about the Challenged Products describe the products' effects on the "structure or function" of the body, and that their "claims" consist of the language of the various product descriptions in their advertising. RPFF Nos. 22-26; *see also* RRFF No. 153 (replying that the "statement cited . . . specifically does not state that the products can cure, treat or prevent cancer"); RB at 9 ("Nowhere on the face of the actual statements by Respondents do Respondents state that their products diagnose, mitigate, treat, cure or prevent a specific disease or class of diseases . . . "). Respondents' arguments disregard both the law and common sense, which recognize that claims may be either express or implied. *In re Kraft, Inc.*, No. 9208, 114 F.T.C. 40, 120, 1991 FTC LEXIS 38, at *10 (Jan. 30, 1991), *aff'd*, 970 F.2d 311 (7th Cir. 1992); *In re Thompson Medical*, 104 F.T.C. at 788, 1984 FTC LEXIS 6, at *311. While express claims directly state the representation at issue, implied claims do so in an oblique or indirect way. *Kraft v. FTC*, 970 F.2d at 318 n.4; *In re Thompson Medical*, 104 F.T.C. at 788, 1984 FTC LEXIS 6, at *312 ("Implied claims are any claims that are not express.").

The primary evidence of the claims an advertisement conveys to reasonable consumers is the advertisement itself. *In re Telebrands Corp.*, No. 9313, 140 F.T.C. 278, 290, 2005 FTC LEXIS 178 (Sept. 19, 2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006); *In re Novartis Corp.*, No. 9279, 127 F.T.C. 580, 680, 1999 FTC LEXIS 90, at *37-38 (May 13, 1999); *In re Kraft*, 1991 FTC LEXIS 38, at *12. Moreover, the Commission looks to the overall net impression created by the advertisement as a whole, by examining the interaction of all of the different elements in the advertisement, rather than focusing on the individual elements in isolation. *American Home Prods. Corp. v. FTC*, 695 F.2d 681, 687 (3d Cir. 1982); *In re Kraft*, 1991 FTC LEXIS 38, at *14; *In re Thompson Medical*, 104 F.T.C. at 323 n.17, 1984 FTC LEXIS 6, at *324 n.17. "[T]he cardinal factor is the probable effect which the advertiser's handiwork will have upon the eye and mind of the reader. It is therefore necessary in these cases to consider the advertisement in its entirety and not to engage in disputatious dissection. The entire mosaic should be viewed rather than each tile separately. 'The buying public does not ordinarily carefully study or weigh each word in an advertisement. . . .'" *FTC v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963) (quoting *Aronberg v. FTC*, 132 F.2d 165, 167 (7th Cir. 1942)).

Assessing the overall net impression of an advertisement includes examining the interaction of such elements as language and visual images. *In re Telebrands*, 140 F.T.C. at 290; *In re Kraft*, 1991 FTC

LEXIS 38, at *13. Testimonials are also a key element in the overall net impression of an advertisement. *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 125 (D. Conn. 2008) ("[W]hen an advertisement contains a testimonial reflecting the experience of an individual with a product, there is an implicit representation that such experience reflects the typical or ordinary results anyone may anticipate from use of the product.") (quoting *Porter & Dietsch, Inc.*, 90 F.T.C. 770, 1977 FTC LEXIS 11, at *147 (1977)). Testimonials not only make representations about the advertised product, but also reinforce representations implied through other elements of the advertisement. *See FTC v. QT, Inc.*, 448 F. Supp. 2d at 920-21, 929-32.

In addition, an advertisement may convey numerous representations, and the same advertising elements may be amenable to more than one reasonable interpretation. *In re Kraft*, 1991 FTC LEXIS 38, at *11 n.8; *In re Thompson Medical*, 104 F.T.C. at 789 n.7, 1984 FTC LEXIS 6, at *312 n.7. Moreover, the representations alleged in the Complaint need not be the only reasonable interpretations of the challenged advertising. *In re Kraft*, 1991 FTC LEXIS 38, at *11 n.8; *In re Thompson Medical*, 104 F.T.C. at 789 n.7, 1984 FTC LEXIS 6, at *312 n.7; *In re Bristol-Myers Co.*, 102 F.T.C. at 320, 1983 FTC LEXIS 64, at *249. In addition, "[s]tatements susceptible of both a misleading and a truthful interpretation will be construed against the advertiser." *FTC v. Bronson Partners*, 564 F. Supp. 2d at 127 n.6 (quoting *Country Tweeds, Inc. v. FTC*, 326 F.2d 144, 148 (2d Cir. 1964)).

As more fully discussed below, based on the overall net impression of the DCO advertisements for the Challenged Products, taken as a whole, the advertisements make the claims alleged in the Complaint. If not expressly made, these claims are clearly implied through the interaction of the advertising's words, visual images, and testimonials. In some cases, the representations are so strongly implied as to be virtually synonymous with express claims.

a. Claims regarding the Challenged Products collectively

(1) "Cancer News" webpage on www.danielchapterone.com

DCO advertises the Challenged Products as a group on the DCO Website on a page entitled "Cancer News." F. 179-88. Viewing the Cancer News webpage as a whole, the claim that the Challenged Products prevent, treat, or cure cancer is so strongly implied as to be virtually express. F. 189.

First, the title of the page, in bold type, is "Cancer News." F. 179. Then, the opening paragraph recommends the Challenged Products "[i]f you suffer from any type of cancer." F. 180. Next, the Challenged Products are prominently featured in a photograph adjacent to the bold type phrase "Daniel Chapter One Cancer Solutions." F. 180. Next, adjacent to the text and visual image are bold type instructions to read or listen to testimonials "about cancer." F. 182, 186-87. The audio testimonials include such titles as, "Marie

– Dad's throat tumor cured – 7 Herb and more," "Nancy – Cured Breast Cancer in 3 months – 7 Herb and GDU," and "Robert -Prostate cured from DC1 products." F. 187. Written testimonials also appear on the webpage. F. 182-85. These include statements from "Tracey," a purported cancer patient on whom "doctors had . . . given up," that she took BioMixx, 7 Herb Formula, and BioShark, among other DCO products, and that she is "now in complete remission." F. 184. Another testimonial states: "After using 7 Herb and other DC1 products for precancerous growths," among other ailments, her X-ray "showed nothing there." F. 185.

The overall net impression from the interaction of the words, pictures, and testimonials is unmistakable – that the Challenged Products prevent, treat, or cure cancer. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *50-52 (holding that advertisement which included statements that herbal supplement was a "solution" for obesity and "Try Thermalean today and win the battle against obesity" clearly implied that the herbal supplement was an effective treatment for obesity).

(2) "Cancer Treatment" advertisement on www.dc1pages.com

The Challenged Products are advertised as a group on the DCO website www.dc1pages.com. F. 190. The words "Cancer Treatment," in bold and larger

type, are featured prominently next to a picture of bottles of the Challenged Products and a listing of their product names. F. 190. The overall net impression of these words and visual images is that the Challenged Products are effective in the treatment of cancer. F. 191.

Respondents contend that use of the phrase "supporting products" at the top of the webpage "indicate[s] that these products are 'supporting products' that can be used in conjunction with cancer treatments, whatever those may be." RRFF No. 137. This contention is belied by the words of the advertisement itself, which states: "To enhance *7 Herb Formula's healing quantities* Daniel Chapter One advises to get familiar with *the supporting products below*." F. 190 (emphasis added). It is clear from this language that the only "cancer treatment" that the Challenged Products are advertised to "support" is DCO's 7 Herb Formula.

(3) "The Most Simple Guide to the Most Difficult Diseases"

The Challenged Products are promoted collectively in the DCO publication, "The Most Simple Guide to the Most Difficult Diseases: The Doctors' How-To Quick Reference Guide." F. 192. The page of the Guide that is dedicated to cancer, which word appears in large, bold type, lists the four Challenged Products in bold type, along with dosing instructions, such as: "7*Herb Formula ™ 2 ounces in juice or

water (minimum intake) 2 times daily." F. 192. Each product listing is preceded by a "sun" symbol which, according to the advertisement, means that this product is "essential" for cancer. F. 192. Through the interaction of these words and visual images, the message that the Challenged Products treat or cure cancer is so strongly implied as to be virtually express. F. 193.

(4) Cancer Newsletter

The Cancer Newsletter, viewed as a whole, conveys the overall net impression that the Challenged Products prevent, treat, or cure cancer. First, the title of the publication, "How to fight cancer is your choice," F. 194, sets the stage by strongly implying, if not expressly stating, that the products described in the newsletter will "fight" cancer. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *50-52 (holding that advertisement which included statement regarding herbal supplement, "Try Thermalean today and win the battle against obesity" clearly implied that the herbal supplement was an effective treatment for obesity). In addition, the preface to the Cancer Newsletter quotes a book entitled "Back to Eden," in which the writer states that his "cure for cancer" includes herbs. This in turn implies that the herbal supplements featured in the Cancer Newsletter can cure cancer. F. 196. Against this backdrop, featuring the Challenged Products, as four of only eight products featured in the Cancer Newsletter,

implies that the Challenged Products treat or cure cancer F. 195, 197, 202.

Further creating and reinforcing this overall net impression are the numerous testimonials to the successful use of the Challenged Products for cancer. F. 197-201. While there are only eight product descriptions, there are seventeen testimonials, which at times appear two to a page. The testimonial titles stand out in large, bold type: "Lump is gone without dangerous surgery!," "7 Herb Formula battles cancer," "7 Herb eliminates pre-cancerous growth," "Ancient cancer remedy improved upon," "Doctors gave up on Michigan man," "Pre-Cancerous Growths & Acid and Heartburn," "Tumor Free!," and "Declared Free of Cancer." F. 198. The testimonials include such statements as: "I started taking the 7 Herb and that tumor was shrinking . . . there has been massive tumor shrinkage." F. 199 ("Doctors gave up on Michigan man"); "Tricia convinced [them] that [the] best hope was to take natural remedies rather than go under the knife. . . . The growth is gone. . . ." F. 199 ("Cancer Success a Lie!"); and, "With stage 4 cancer and given only 6 months to live, Joe's dad was not doing well. . . . With 4 ounces of 7*Herb a day, in just 2 days . . . the family watched dad's color come back. . . . GDU to the rescue! . . . PSA 3.3, no pain, alive. . . ." F. 199 ("Not too late!").

By including the Challenged Products prominently and referring to them in the testimonials, the Cancer Newsletter implies that the Challenged

Products, individually or in combination with one another, prevent, treat, or cure cancer. F. 202.

(5) BioGuide

Like the Cancer Newsletter, the BioGuide makes prominent, overwhelming use of testimonials claiming the successful use of the Challenged Products for cancer. F. 203. The clear implication of the BioGuide, through the words, photographs, and testimonials in particular, is that the Challenged Products prevent, treat, or cure cancer. F. 211. For example, on the page immediately following an advertisement for 7 Herb Formula, there is a picture of a smiling woman and the heading in large, colored, and bold type, "Cancer Brain Tumor." Next to that entry is the colored, italicized text:

> *The doctors had pretty much given up on Tracey. She had leukemia and tumors on the brain, behind the heart and on her liver.*

The testimonial then claims that the speaker took "*BIOMIXX* and *7 HERB FORMULA*," which resulted in "complete remission." It further claims that a tumor above the brain stem "completely disappeared," a "tumor on my liver is shrinking and the tumor behind my heart has shrunk over 50%. . . ." F. 204.

Similarly styled claims, complete with photographs of smiling people, are made in testimonials entitled: "Lowered PSA," in which the speaker announces the "GOOD NEWS" of a lowered PSA, and states his belief that 7 Herb Formula and GDU "did

the trick," F. 205; "Prostate Cancer," in which the author claims that he took 7 Herb Formula and BioMixx, has a lowered PSA, and plans to "stay on [7 Herb Formula] forever!" apparently to keep his cancer at bay, F. 206; and "Renal Cell Cancer," in which the speaker claims to be taking 7 Herb Formula, GDU, and BioShark, and that "no further activity" in his kidney tumor has occurred. F. 207. The BioGuide also includes a testimonial from a doctor who claims to have given 7 Herb Formula, BioShark, and GDU to his own child and claims the child's tumor has "begun to shrink. . . . Four months later the whole family is using the products, as well as my patients," F. 209, with the clear implication that these products have the ability not only to cure cancer, but to prevent it as well. Read as a whole, through the interaction of the product descriptions, the visual images, such as highlighted text and photographs, and the testimonials, the BioGuide clearly implies, if not expressly states, that the Challenged Products prevent, treat, or cure cancer. F. 211.

b. Claims regarding BioShark

(1) Website advertising

The product description of BioShark on the DCO Website states in pertinent part:

> Pure skeletal tissue of sharks which provides a protein that inhibits angiogenesis – the formation of new blood vessels. This can stop tumor growth, and halt the progression of

> eye diseases such as diabetic retinopathy and macular degeneration. . . .

F. 221. Respondents assert that the foregoing statements comprise their entire advertising "claim" for BioShark. *See* RPFF No. 22. Even standing alone, the product description, through the use of such phrases as "inhibits angiogenesis" and "can stop tumor growth," strongly implies that BioShark inhibits tumors. F. 222. The language does not stand alone, however, and must be interpreted in the context of the other elements of the advertisement to determine the overall net impression. *See American Home Prods. v. FTC*, 695 F.2d at 687 (stating that advertisement must be interpreted as a whole, without emphasizing isolated words or phrases apart from their context). In this advertisement, the product webpage specifically promotes BioShark, in bold letters, for "Tumors & Cysts." F. 221. Adjacent to the product description is the message: "Read our clients [sic] testimonials on BioShark & Tumors," and a link to a bulleted title, "Cancerous Tumor." F. 221. At the bottom of the webpage is a link to "Stop Tumor Growth & Cysts Top." F. 221. Considering these additional elements, the overall net impression of the product webpage for BioShark is that BioShark inhibits cancerous tumors and is an effective treatment for cancer. F. 224.

Adding to the overall net impression of the DCO Website that BioShark inhibits cancerous tumors and is an effective treatment for cancer, is that BioShark is featured as one of the "cancer solutions" for "any type of cancer" on the Cancer News webpage. F. 180.

The website www.dc1pages.com also expressly advertises BioShark, along with the other Challenged Products, as a "Cancer Treatment." F. 190.

Further adding to that overall net impression is the following statement, set forth under the BioShark heading, which implies that BioShark inhibits tumors: "In 1983, two researchers at the Massachusetts Institute of Technology published a study showing that shark cartilage contains a substance that significantly inhibits the development of blood vessels that nourish solid tumors, thereby limiting tumor growth. This effect is called anti-angiogenesis." F. 225.

It is not a defense that the advertisements attempt to tie claims to the constituent ingredients of BioShark, i.e., "skeletal tissue of sharks" and "shark cartilage," as opposed to BioShark itself because, despite this word parsing, the overall net impression is that Respondents' claims pertain to the BioShark product itself. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *53-55 (holding that even though express language of the advertising attempted to tie a claim to components of herbal supplement product and not to the product itself, the overall net impression was a claim as to the effectiveness of the product itself).

(2) Cancer Newsletter

The overall net impression from the Cancer Newsletter is that BioShark inhibits tumors and is effective in the treatment of cancer. F. 232. BioShark

is among the products that the Newsletter's title represents will "fight" cancer. F. 195, 197. Moreover, BioShark is specifically included in numerous testimonials. E.g., F. 184 ("7 Herb Formula battles cancer" ("[M]y father sent me BIOMIXX and 7 HERB FORMULA. Each day as I took it and got it into my system more and more, the better I felt. Then I added Garlic Pur, Siberian Ginseng, and Bio*Shark. I am now in complete remission.")); F. 200 ("Texas businessman has true friends for life" (Friends send a bladder cancer sufferer a package that "included 7 Herb Formula . . . Bio*Shark and Bio*Mixx"), and "Tumor Free!" (claiming that brain cancer sufferer takes "7 HERB FORMULA . . . BIO MIXX, BIO SHARK, and GDU Caps: . . . [T]he tumors were completely gone.")).

In addition, the Cancer Newsletter includes representations implying that BioShark has been scientifically proven to inhibit tumors, repeating the statement from the Cancer News webpage on the DCO Website: "In 1983, two researchers at the Massachusetts Institute of Technology published a study showing that shark cartilage contains a substance that significantly inhibits the development of blood vessels that nourish solid tumors, thereby limiting tumor growth. This effect is called anti-angiogenesis." F. 231. Adding to and strengthening this impression is the placement of this paragraph in the midst of the large, bold, and highlighted type testimonial titles, "Doctors gave up on Michigan Man" and "Pre-Cancerous Growth & Acid and Heartburn." F. 231.

(3) BioGuide

The BioGuide contains the same product description for BioShark as that found on its product webpage on the DCO Website. F. 221, 228. For the same reasons as those stated above, that product description strongly implies that BioShark inhibits tumors. F. 229. Adding to and reinforcing that implied claim are the testimonials, complete with photographs of smiling people, claiming that BioShark effectively treated cancer. For example, the testimonial "Cancer Brain Tumor" includes the statement: "[M]y father sent me *BIOMIXX* and *7 HERB FORMULA*. Each day as I took it and got it into my system more and more, the better I felt. Then I added Garlic, Siberian Ginseng, and BioShark. I am now in complete remission." F. 204. Similarly, the testimonial entitled "Renal Cell Cancer" includes the following: "I had Renal Cell Cancer in my left kidney, with a tumor attached that was slightly larger than a baseball. I went on 7 Herb Formula and GDU. . . . I continue to drink the 7-Herb and take Bio-Shark, and GDU. . . . [N]o further activity has occurred." F. 207. Another testimonial claims: "After switching to DC1 products – 7-Herb Formula, BioShark, GDU, Garlic Pur, Siberian Ginseng, Ezekiel Oil and BioMixx – [the skin cancer] cleared up quickly. . . . [T]hree weeks ago [I] was told I was completely clear of all types of cancer." F. 208. Accordingly, the BioGuide, taken as a whole, through the interaction of the product descriptions, the visual images such as highlighted text and photographs, and the testimonials, not only represents that

BioShark inhibits tumor growth, but that BioShark prevents, treats, or cures cancer. F. 230.

(4) BioMolecular Nutrition Product Catalog

The BioMolecular Nutrition Product Catalog includes a similar product description for BioShark as that set forth on the DCO Website and in the BioGuide, stating: "Shark Cartilage protein inhibits angiogenesis, stops tumor growth, and halts eye diseases. Reduces pain, inflammation, joint stiffness of arthritis, inflammatory bowel disease, and reverses psoriasis. Affects the formation of new blood vessels." F. 233; *see* F. 221, 228. The overall net impression of this description is that BioShark inhibits tumor growth. F. 235. Indeed, the phrase "stops tumor growth" expressly claims that BioShark inhibits tumor growth. F. 234.

c. Claims regarding 7 Herb Formula

(1) Website advertising

The product page for 7 Herb Formula includes in the description, "purify the blood and promote cell repair. The ingredients in this tea concentrate work to clear skin, cleanse the liver, decrease cell mutation, and fight pathogenic bacteria and tumor formation." F. 237. The product is also featured on the Cancer News webpage of the DCO Website with a similar description, stating that 7 Herb Formula "purifies the blood, promotes cell repair, fights tumor formation

[and] fights pathogenic bacteria." F. 238. Respondents focus on these statements, asserting that the statements comprise their website "claim" regarding 7 Herb Formula. Relying on these statements alone, Respondents assert that they did not claim that 7 Herb Formula treats, cures, or prevents cancer. RPFF No. 23. Contrary to Respondents' position, such statements as "fights tumor formation" and "decrease[s] cell mutation," by themselves clearly do imply that 7 Herb Formula inhibits tumors and treats cancer. F. 239.

Moreover, the words do not appear in isolation, but interact with other elements in the advertisement. First, the product description appears under a bold type heading including the words "Cancer Help." F. 237. Next, a picture of the product with its description appears first on the Cancer News webpage, where the phrase "fights tumor formation" is highlighted in bold type. F. 238. Next, after the product description and a photograph of the product along with the other Challenged Products, is the admonition, "How to fight cancer is your choice!" F. 240. In addition, there are links to testimonials "about cancer," with titles that include specific references to 7 Herb Formula, such as "7 Herb Formula battles cancer" and "7 Herb eliminates pre-cancerous growth." F. 241. These elements interact to create a strong impression that 7 Herb Formula not only inhibits tumor growth, but is an effective treatment for cancer.

The text of testimonials strengthens this impression. For example, in the testimonial entitled "7 Herb Formula Battles Cancer," the speaker claims taking

7 Herb Formula, among other DCO products, for cancer and experiencing a "complete remission," thereby creating the impression that 7 Herb Formula cured her. F. 184; *see also* F. 243 (describing Michigan man's claim of taking 7 Herb Formula and experiencing "massive tumor shrinkage"). In addition, the testimonial entitled "7 Herb Eliminates Pre-cancerous Growth" states in part, "I had a pre-cancerous 'wart' on the back of my leg and drinking 7 Herb Formula made it go away," thereby creating the impression that 7 Herb Formula prevents cancer. F. 242.

Other material on the DCO Website further contributes to the overall net impression that 7 Herb Formula is an effective cancer treatment. The Cancer News webpage article, "Ancient Cancer Remedy is Improved Upon," includes statements that "Jim improved upon the ancient Ojibway Indian Tribe remedy known as Essiac. . . . As a result of his research, Jim found that by adding Siberian Ginseng and Cat's Claw to the Essiac formula, he could attain remarkable healing results. . . ." F. 242; *see also* F. 244 ("With Jim Feijo's addition to the [7 Herb] formula, we now have the most effective and potent formula available in the battle against tumors."). Such statements clearly imply, if not expressly represent, that 7 Herb is an effective cancer remedy. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *51-52 (holding that advertisement which included statements that herbal supplement was the "most complete . . . nutriceutical ever developed for the diet

industry" implied that the herbal supplement was an effective treatment for obesity).

The DCO website www.dc1pages.com expressly advertises 7 Herb Formula, along with the other Challenged Products, as a "Cancer Treatment" and specifically refers to its "healing qualities." F. 190. In addition, the question and answer portion of this site, similar to that on the DCO Website, makes the claim that 7 Herb Formula is the "most effective and potent formula available in the battle against tumors," F. 246, and therefore similarly represents that 7 Herb Formula is an effective cancer remedy. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *51-52 (holding that advertisement which included statements that herbal supplement product was the "most complete . . . nutraceutical ever developed for diet industry" implied that the herbal supplement was an effective treatment for obesity). Finally, the website www.dc1pages.com states that 7 Herb Formula has been used in cancer clinics and provided in doctor's offices, thereby creating the impression that 7 Herb Formula is a cancer treatment. F. 247. Viewed in its entirety, the overall net impression of the advertising for 7 Herb Formula on www.dc1pages.com is that the product inhibits tumors and is effective for the treatment of cancer. F. 248.

(2) Cancer Newsletter

The product description for 7 Herb Formula in the Cancer Newsletter states that 7 Herb Formula

"fights . . . tumor formation." F. 251. Accordingly, the advertisement clearly implies that the product inhibits tumor formation. Combined with the statements that "7 Herb Formula has been created to . . . promote cell repair . . . fights pathogenic bacteria . . . [t]he ingredients . . . decrease cell mutation," the product description also implies that 7 Herb Formula is effective in treating cancer. F. 251, 255. The advertisement also states, immediately below the product description under a heading, in large, bold type, "esophageal cancer?" that the ingredients of 7 Herb Formula "may prevent and even heal cancer." F. 252. These statements strongly imply, if not expressly state, that 7 Herb Formula prevents or cures cancer. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *53-55 (holding that even though the express language of advertising attempted to tie a claim to components of herbal supplement product and not to the product itself, overall net impression was a claim as to the effectiveness of the product itself).

Moreover, the above product descriptions must be interpreted with reference to other elements of the Cancer Newsletter. First, 7 Herb Formula is included among the eight products that the Cancer Newsletter's title represents will "fight" cancer. F. 195, 197. In fact, the Cancer Newsletter particularly highlights 7 Herb Formula, devoting an entire page to the product and prominently featuring its logo. F. 251. In addition, several testimonial titles specifically refer to 7 Herb Formula. E.g., F. 184 ("7 Herb Formula

battles cancer"); F. 198 ("7 Herb Formula Eliminates Pre-Cancerous Growth"); F. 253 (same); F. 204 ("My father sent me BIOMIXX and 7 HERB FORMULA. Each day as I took it and got it into my system more and more, the better I felt. . . . I am now in complete remission"); F. 242 ("I had a pre-cancerous 'wart' on the back of my leg and drinking 7 Herb Formula made it go away"); and F. 253 ("7 Herb Formula Helps Battle Cancer" ("Within 60 days [of being on 7 Herb Formula] . . . PSA level dropped from 256 to 5. . . . [Thereafter, n]o evidence of . . . tumor.")).

The interaction of all of the elements of the Cancer Newsletter, including the title of the publication, the prominent featuring of 7 Herb Formula in text, visual imagery, and testimonials, and the content of the product descriptions and testimonials, creates an overall net impression that 7 Herb Formula inhibits tumors and is effective to prevent, treat, or cure cancer. F. 255.

(3) BioGuide

The product description for 7 Herb Formula in the BioGuide, mirroring that on the DCO Website, includes the statements: "Herbs to purify the blood and promote cell repair. The ingredients in this tea concentrate work to clear skin, cleanse the liver, decrease cell mutation, and fight pathogenic bacteria and tumor formation." F. 237, 249. As on the DCO Website, these statements do not stand alone.

The product description is repeated twice in the three pages devoted to 7 Herb Formula. F. 249. Moreover, in between these pages is a page containing two testimonials to 7 Herb Formula. The first testimonial, "Cancer Brain Tumor," shows a smiling woman next to text highlighting the use of 7 Herb Formula in sending her cancer into "complete remission" and shrinking other tumors. F. 249. The placement and title of the second testimonial, "Lowered PSA," itself implies that 7 Herb Formula is related to the reported improvement in that cancer indicator. The testimonial features a photograph of a smiling man and text expressly stating the speaker's belief that the DCO products he took, including 7 Herb Formula, "did the trick." F. 205. Other testimonials in the BioGuide make similar claims as to the effectiveness of 7 Herb Formula to prevent, treat, or cure cancer. *See, e.g.*, F. 206 (testimonial entitled "Prostate Cancer," stating that the speaker took 7 Herb Formula "every day. . . . [It] did such a good job fighting cancer, 2 ounces is a good prophylaxis!"); F. 207 (testimonial entitled "Renal Cell Cancer," stating that the speaker with cancerous kidney tumor went on 7 Herb Formula and the oncologist is "amazed that no further activity has occurred"); F.208 (testimonial entitled "Skin Cancer," in which the speaker switches to DCO products, including 7 Herb Formula, and is "completely clear of all types of cancer").

The overall net impression from the BioGuide, through the interaction of the words of the product descriptions, the visual images such as highlighted

text and photographs, and the testimonials, is that 7 Herb Formula inhibits tumors and is effective to prevent, treat, or cure cancer. F. 250.

(4) BioMolecular Nutrition Product Catalog

The BioMolecular Nutrition Product Catalog describes 7 Herb Formula in virtually the same manner as the DCO Website, the BioGuide, and the Cancer Newsletter, stating that the herbs in 7 Herb Formula "purify the blood and promote cell repair, clear skin, cleanse the liver, decrease cell mutation, [and] fight pathogenic bacteria and tumor formation." F. 237, 249, 251, 256. As noted above, use of the phrase, "fights . . . tumor formation" strongly implies, if not expressly states, that the product inhibits tumor formation. Combined with the phrases "promote cell repair," "decrease cell mutation," and "fight pathogenic bacteria," the product description as a whole implies that 7 Herb Formula is effective in treating cancer. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *53-55 (holding that even though express language of advertising attempted to tie a claim to components of herbal supplement product and not to the product itself, overall net impression was a claim as to the effectiveness of the product itself).

d. Claims regarding GDU

(1) Website advertising

The product page for GDU on the DCO Website includes statements that the ingredients of GDU "digest protein – even that of unwanted tumors and cysts" and that GDU is used "as an adjunct to cancer therapy." F. 262-63. These statements imply that GDU inhibits tumors and is a cancer treatment. F. 264. In addition, the product webpage has links to testimonials with various cancer-related titles, including, "Breast Mass" and "Prostate Cancer." F. 265. The interaction of the product description and cancer-related testimonial titles gives this DCO Website advertisement a strong overall net impression that GDU not only inhibits tumors, but is an effective cancer treatment or cure. F. 269.

Other features on the DCO Website strengthen this impression. GDU is featured as a "Cancer Solution" for "any type of cancer" on the Cancer News webpage on the DCO Website, further reinforcing the implication that GDU is an effective cancer treatment. F. 266. Testimonials on that webpage, or linked to the webpage, also claim that taking GDU, along with other DCO products, effectively treated cancer. F. 267; F. 268 ("Nancy – Cured Breast Cancer in 3 months – 7 Herb and GDU" and "Mel – Breast Mass [illegible] and GDU"). This website advertising also creates the impression that GDU is an effective cancer treatment. F. 269.

The DCO website www.dc1pages.com also claims that GDU is an effective treatment by expressly advertising GDU, among the other Challenged Products, as a "Cancer Treatment." F. 190.

(2) Cancer Newsletter

The product description for GDU in the Cancer Newsletter appears under the headline in large, bold type: "Enzymes attack growths." F. 276. The advertisement goes on to explain how the enzymes in GDU "can aid the body in breaking down a tumor." F. 276. It emphasizes the importance of enzymes "in treating cancer," stating that such enzymes can return leukemia cells "to a normal state," and help "to destroy cancer cells." F. 276. While these statements ostensibly refer only to the enzyme ingredient in GDU, they impliedly represent that GDU itself has these cancer treating qualities. F. 277. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *53-55 (holding that overall net impression was a claim as to the effectiveness of the product itself, even though express language of advertising attempted to tie claims to components of herbal supplement product and not to the product itself).

Even though the language of the product description for GDU in the Cancer Newsletter attempts to relegate GDU's claimed effectiveness to a supporting role in "helping" or "aiding" the body, "[t]he entire mosaic should be viewed rather than each tile separately." *FTC v. Sterling Drug*, 317 F.2d at 674. In this

case, the entire mosaic of the advertisement belies a merely "supporting" role for GDU. The overall net impression is that GDU itself inhibits tumors and is an effective cancer treatment. F. 278.

GDU is one of the eight products that the Cancer Newsletter's title represents will "fight" cancer. F. 195, 197. The product description appears under the heading in large, bold type: "Enzymes attack growths." F. 276. Adjacent to the GDU headline, photograph, and product description are two testimonials with large type, highlighted and bold headlines: "Lump is gone without dangerous surgery" and "Cancer Success a Lie!" F. 276. Other testimonials in the Cancer Newsletter claim that taking GDU, along with other DCO products, effectively treats cancer. F. 200 ("Tumor Free!" claims brain cancer sufferer takes "7 HERB FORMULA . . . , BIO MIXX, BIO SHARK, and GDU Caps . . . [and thereafter] the tumors were completely gone"); and F. 199 ("Not too late!" in which a stage-four cancer patient with six months to live announces, "GDU to the rescue!").

The interaction of all of the elements of the Cancer Newsletter, including the title of the publication, the featuring of GDU, the product description headline and text, and the titles and content of its testimonials, creates an overall net impression that GDU inhibits tumors and is an effective cancer treatment. F. 278.

(3) BioGuide

The BioGuide features the product description for GDU on two pages. F. 270. The descriptions track those on the DCO Website and in the Cancer Newsletter, stating that GDU contains enzymes "to help digest protein – even that of unwanted tumors and cysts," and that GDU has a variety of uses, including "as an adjunct to cancer therapy." F. 263, 270-71. The former statement is repeated in large, bold type, thereby emphasizing the purported ability of GDU to "digest . . . tumors and cysts." F. 271. Taken as a whole, this product description implies that GDU inhibits tumors and implies that GDU is a cancer treatment. F. 272.

There are additional elements in the BioGuide that create the overall net impression that GDU inhibits tumors and is an effective treatment for cancer. The product name "GDU," in large, bold type, and the statement, also in large, bold type, regarding its effect on "tumors and cysts," appear above a photograph of a smiling man, and the large, bold type testimonial title, "Prostate Cancer." F. 271.

Moreover, testimonials in the BioGuide discuss the use of GDU in treating cancer. For example, on the page immediately following the GDU product description, the testimonial entitled "Breast Mass" claims that after discovering a breast mass, the speaker "began taking GDU six times a day. . . . I got another bottle of GDU and the Superior Herbal Fat Burners, which I took twice a day. In April I had my

6-month examination and the letter read: 'We are pleased to inform you that the results of your recent breast evaluation are normal.'" F. 273. Similarly, the testimonial entitled "Renal Cell Cancer" describes the speaker's use of GDU for a kidney tumor: "I went on 7 Herb Formula and GDU. . . . I continue to drink the 7-Herb and take Bio-Shark, and GDU. . . . To date, my oncologist is amazed that no further activity has occurred." The latter statement is repeated in large, bold type. F. 207. In addition, the testimonial entitled "Lowered PSA" announces the speaker's "GOOD NEWS" of a lowered PSA after taking "7 Herb formula, in combination with your Bio C 1000, GDU and other minerals and vitamins. I believe it was your products that did the trick." F. 274; *see also* F. 208 ("Skin Cancer": "After switching to DC1 products – 7-Herb Formula, BioShark, GDU, Garlic Pur, Siberian Ginseng, Ezekiel Oil and BioMixx – it cleared up quickly . . . completely clear of all types of cancer"); F. 209 ("My son was diagnosed with a tumor on his left temple. . . . Jim and Trish . . . suggested 7-Herb, BioShark and GDU, which we bought and started him on. . . . [T]he tumor had already begun to shrink. . . . Four months later the whole family is using the products, as well as my patients, and you would never know my son had a tumor"); F. 210 ("One lady, who had a history of cancer, used the 7 Herb Formula, GDU & BioShark and was blessed to get rid of a large breast tumor.").

The interaction of all of the elements of the BioGuide regarding GDU, including the product

descriptions, the visual images, such as highlighted text and photographs, and the testimonials, create the overall net impression that GDU inhibits tumors and is an effective cancer treatment. F. 275.

(4) BioMolecular Nutrition Product Catalog

The product description for GDU in the BioMolecular Nutrition Product Catalog mirrors that in the other DCO publications, stating that GDU contains enzymes "to help digest protein, even that of unwanted tumors and cysts. Helps to relieve pain, inflammation, and as an adjunct to cancer therapy." F. 263, 270, 276, 279. As stated above, taken as a whole, this product description implies that GDU inhibits tumors and is a cancer treatment. F. 280-81.

e. Claims regarding BioMixx

(1) Website advertising

Both the DCO Website and the website www.dc1pages.com imply that BioMixx is effective in treating or curing cancer. The Cancer News webpage on the DCO Website expressly advertises BioMixx, along with the other Challenged Products, as a "Cancer Solution" for "any type of cancer." F. 283. The Cancer News webpage also includes a testimonial representing that BioMixx effectively treated cancer: "I had contracted leukemia and had three inoperable tumors. When I decided not to do chemotherapy or radiation, my father sent me Bio*Mixx and 7 Herb

Formula. Each day as I took it and got it into my system more and more, the better I felt. . . . I am now in complete remission." F. 284. The website www.dc1pages.com also claims that BioMixx is an effective cancer treatment by expressly advertising BioMixx, among the other Challenged Products, as a "Cancer Treatment." F. 285.

(2) Cancer Newsletter

The product description for BioMixx in the Cancer Newsletter claims that BioMixx "is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments." F. 293. As with the similar word parsing used for the product descriptions for GDU (*see* F. 276), Respondents' attempt to relegate BioMixx's effectiveness to a supporting role in assisting the body fails. It is necessary to consider the advertisement "in its entirety and not to engage in disputatious dissection." *FTC v. Sterling Drug*, 317 F.2d at 674. In this case, the "entire mosaic" of the Cancer Newsletter creates the overall net impression that BioMixx is an effective cancer treatment and ameliorates the adverse effects of radiation and chemotherapy. F. 294.

BioMixx is one of the eight products that the Cancer Newsletter's title represents will "fight" cancer. F. 195, 197. In addition, BioMixx is among the products referred to in the testimonial "7 Herb Formula Battles Cancer," in which the speaker is quoted as saying: "I had contracted leukemia and had three

inoperable tumors. When I decided not to do chemotherapy or radiation, my father sent me Bio*Mixx and 7 Herb Formula. Each day as I took it and got it into my system more and more, the better I felt. . . . I am now in complete remission." F. 292. Viewing the Cancer Newsletter as a whole, and considering the interaction of the publication's title, the BioMixx product description, and the testimonial, the overall net impression is that BioMixx is an effective cancer treatment and heals the adverse effects of radiation and chemotherapy. F. 294.

(3) BioGuide

The lengthy product description for BioMixx in the BioGuide states in relevant part that BioMixx "[h]elps detoxify the body [and] boosts immunity and energy. . . . What separates BioMixx is that it was developed specifically to maximize the immune system, particularly for those individuals whose immune systems were compromised through chemotherapy and radiation. . . . This scientifically designed formula provides your body with [herbs and nutrients] . . . for cell, organ, and tissue health. . . . Whether you're losing weight battling illness, or are weakened due to intense training, BioMixx is the best." F. 287. This description conveys the clear message that BioMixx is an effective treatment for the adverse effects of chemotherapy and radiation. F. 288. By juxtaposing the promotion of BioMixx for this purpose with the promotion of BioMixx for "cell" health and to "battle illness," the advertisement also conveys the impression that BioMixx is effective for cancer. F. 291.

The impression that BioMixx is an effective cancer treatment, as well as an antidote to the adverse effects of chemotherapy and radiation, is strengthened by the message of testimonials. For example, the testimonial entitled "Cancer Brain Tumor" appears prominently, next to a photo of a smiling woman, and includes the statements: "I had contracted leukemia and had three inoperable tumors. When I decided not to do chemotherapy or radiation, my father sent me *BIOMIXX* and *7 HERB FORMULA*. Each day as I took it and got it into my system more and more, the better I felt. . . . I am now in complete remission. . . ." F. 204, 289. BioMixx is also featured in a prominent testimonial entitled "Prostate Cancer," which states in part: "I had beam radiation for prostate cancer. I also took 7 Herb Formula . . . and BioMixx; I never had a bad day, never felt sick. When my PSA went from 7.6 to 0.5 in the month after I finished radiation, my doctor was surprised. Several months later it was down to 0.16!" F. 290.

Viewed as a whole, considering the product descriptions, the visual images, such as highlighted text and photographs, and the testimonials, the BioGuide conveys the overall net impression that BioMixx is effective in the treatment of cancer and in healing the adverse effects of radiation and chemotherapy. F. 291.

f. Disclaimer language

Respondents assert that their website advertising contains the following disclaimer: "These statements

have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent disease." RFF 16 (citing CX 17 at FTC-DCO 0073, 0076, 0080, 0084, 0089, 0095, 0098). Respondents' cited disclaimer appears on certain shopping cart webpages on the website www.dc1store.com. F. 301. Relatively similar disclaimers, but briefer and without the FDA reference, appear on the bottom of certain webpages from www.dc1pages.com, at the bottom of webpages on danielchapterone.com, at the end of the BioGuide, and on the last page of the Cancer Newsletter. F. 296-300.

"Disclaimers or qualifications in any particular ad are not adequate to avoid liability unless they are sufficiently prominent and unambiguous to change the apparent meaning of the claims and to leave an accurate impression. Anything less is only likely to cause confusion by creating contradictory double meanings." *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1497 (1st Cir. 1989) (citing *Giant Food, Inc. v. FTC*, 322 F.2d 977, 986 (D.C. Cir. 1963)); *accord FTC v. U.S. Sales Corp.*, 785 F. Supp. 2d. 737, 751 (N.D. Ill. 1992). Applying these standards to evaluate the above disclaimer, as well as similar disclaimers in the DCO advertising materials, it is readily apparent that the disclaimers are ineffective to alter the overall net impression of the advertisements or to leave an accurate impression.

The purported disclaimers are not prominent in any advertisement. In each case, the disclaimer appears well after the conclusion of the advertising

claims. F. 296-300. In each instance, the disclaimer appears in type that is the same size, or smaller, than the surrounding type. F. 296-301, 303. The disclaimer in the Cancer Newsletter is virtually infinitesimal. F. 299, 303. In each instance, except for the webpages cited by Respondents, the disclaimer is buried in copyright disclosures. F. 296-300. Such small-print disclaimers at the bottom of advertisements are insufficient. *See FTC v. Medlab, Inc.*, No. C 08-822 SI, 2009 U.S. Dist. LEXIS 33917, at *15 (N.D. Cal. Apr. 21, 2009) ("Defendants cannot inoculate themselves from the representations that appear in the body of the text by including cautionary statements at the foot of the advertisements.").

Moreover, the language disclaiming any intent to "treat" any disease only serves to confuse in this case by interjecting a message that is contradictory to the overall net impression that the Challenged Products do treat cancer. For example, the disclaimer language appearing on one of the pages of www.dc1pages.com is followed on the next page, in bold type font far larger than that used for the disclaimer, by language touting:

> CANCER TREATMENT
>
> 7 Herb Formula
> Bio*Shark
> BioMixx
> GDU Caps

F. 304.

Because the purported disclaimers are not prominent or unambiguous, and create confusion with messages that contradict the advertisements' overall messages, the disclaimers are ineffective. *See In re Giant Food*, No. 7773, 61 F.T.C. 326, 1962 FTC LEXIS 85, at *51-52 (July 31, 1962) (holding that small print disclaimers that were inconsistent and contradictory to the content of the advertisements were ineffective to cure deceptive advertising), *aff'd*, *Giant Food, Inc. v. FTC*, 322 F.2d 977, 986 (D.C. Cir. 1963); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 924 n.15 (stating that inconspicuous, periodic, on-screen statement in infomercial that "'this product is not intended to diagnose, treat, cure or prevent disease' [was] wholly inadequate to change the net impression of the pain relief claims made"). Accordingly, the disclaimers in Respondents' advertisements in this case are not adequate to avoid liability. *See FTC v. Phoenix Avatar, LLC*, No. 04 C 2897, 2004 U.S. Dist. LEXIS 14717 (N.D. Ill. July 29, 2004) (holding that disclaimer on the back of product packaging, that "[t]hese statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease," did not foreclose liability for deceptive advertising of weight-loss product).

g. Extrinsic evidence is not required

Respondents contend that their advertisements cannot be interpreted through a facial analysis alone, and that extrinsic evidence of consumer perceptions is required in order to find implied claims. RB at 5, 7,

10. Both the Commission and the courts, however, have squarely rejected the notion that extrinsic evidence is always necessary in order to prove an implied claim. As the Commission explained in *Thompson Medical*:

> [T]he Commission employs two different techniques in evaluating whether an advertisement contains implied claims. One is to look at evidence from the advertisement itself. We often conclude that an advertisement contains an implied claim by evaluating the conten[t] of the advertisement and the circumstances surrounding it. This technique is primarily useful in evaluating advertisements whose language or depictions are clear enough, though not express, for us to conclude with confidence after examining the interaction of all the different elements in them that they contain a particular implied claim. If our initial review of evidence from the advertisement itself does not allow us to conclude with confidence that it is reasonable to read an advertisement as containing a particular implied message, we will not find the ad to make the implied claim unless extrinsic evidence allows us to conclude that such a reading of the ad is reasonable.

104 F.T.C. at 789, 1984 FTC LEXIS 6, at *312-13.

In *Kraft v. Federal Trade Commission*, the court affirmed the Commission's holding that Kraft's advertising, which stated that Kraft uses "five ounces of milk" per slice of cheese, implied that its cheese had

the same calcium content as that portion of milk. 970 F.2d at 313. In finding that implied claim, the Commission relied on the advertising itself and did not rely on any extrinsic evidence of consumer perceptions of the advertising. On appeal, Kraft argued that the Commission should be required, as a matter of law, to support its findings with extrinsic evidence in all cases involving implied claims. The court, finding Kraft's argument "unavailing as a matter of law," observed:

> Courts, including the Supreme Court, have uniformly rejected imposing such a requirement on the FTC, and we decline to do so as well. We hold that the Commission may rely on its own reasoned analysis to determine what claims, including implied ones, are conveyed in a challenged advertisement, so long as those claims are reasonably clear from the face of the advertisement. . . . The implied claims Kraft made are reasonably clear from the face of the advertisements. . . . Hence the Commission was not required to utilize consumer surveys in reaching its decision.

970 F.2d at 319-20 (citing *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 391-92 (1965) (stating that the FTC is not required to conduct consumer surveys before determining that a commercial has a tendency to mislead) (other citations omitted)).

In this case, Respondents' advertising claims are even more clearly implied than those in *Kraft*. The interaction of product descriptions, advertisement

headings, visual images, testimonial titles, and testimonial texts, among other elements, is more than sufficient to conclude with confidence that the advertisements at issue make the claims alleged in the Complaint. The implied claims in Respondents' advertising are beyond "reasonably clear." They are clear and conspicuous from the advertising itself. Accordingly, no extrinsic evidence is necessary to interpret the claims. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *42 n.12 (entering summary judgment in false advertising case where facial analysis of dietary supplement advertisements showed clearly implied claims of effectiveness for treatment of erectile dysfunction, holding that extrinsic evidence of consumer perceptions was unnecessary as a matter of law). *See also FTC v. QT, Inc.*, 448 F. Supp. 2d at 958 (stating: "'The courts and the FTC have consistently recognized that implied claims fall along a continuum from those which are so conspicuous as to be virtually synonymous with express claims to those which are barely discernible. It is only at the latter end of the continuum that extrinsic evidence is necessary.'") (quoting *FTC v. Febre*, No. 94 C 3625, 1996 U.S. Dist. LEXIS 9487, at *14 (N.D. Ill. July 3, 1996)).

Respondents contend that extrinsic evidence is particularly necessary in this case because the advertising was targeted at a particular group, defined by Respondents as individuals devoted to natural health in general and the constituents of Respondents' religious ministry in particular. RB at 6-7. While it is

true that, if an advertisement is targeted at a particular group, the Commission analyzes the advertisements from the perspective of reasonable consumers within that group, *In re Telebrands*, 140 F.T.C. at 291, in this case there is insufficient evidence to conclude that Respondents' advertising was directed only at the target group Respondents allege. Rather, the evidence shows that anyone can access the advertisements. The DCO publication, "The Most Simple Guide," is available on the DCO Website and anyone can download it. F. 163. The BioGuide and the Cancer Newsletter are also available on-line through the DCO Website. F. 169, 172. Consumers can locate the DCO Website by entering the term "cancer" in a Google search. F. 162. Moreover, nothing on the DCO Website indicated to the FTC investigator who made the undercover purchase in this case that a consumer would have to be part of any religious community in order to purchase the Challenged Products. F. 149. Accordingly, it is not necessary to interpret Respondents' claims from the perspective of Respondents' purported target group and extrinsic evidence is not necessary for that purpose.

2. Respondents' claims are misleading

There are two theories to prove that an advertisement is deceptive or misleading: (1) the "falsity"

theory[4] or (2) the "reasonable basis" theory. *FTC v. Pantron I*, 33 F.3d at 1096; *In re Thompson Medical*, 104 F.T.C. at 818-19, 1984 FTC LEXIS 6, at *380-81. The Complaint in this case makes allegations only under the reasonable basis theory (Complaint ¶¶ 15, 16) and thus the analysis in this decision considers the reasonable basis theory only.

The reasonable basis theory holds that claims about a product's attributes, performance, or efficacy ("objective" product claims[5]) carry with them the express or implied representation that the advertiser had a reasonable basis substantiating the claims at the time the claims were made. *In re Thompson Medical*, 104 F.T.C. at 813, 1984 FTC LEXIS 6, at *367; *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 298; *In re Kroger*, No. C-9102, 1978 FTC LEXIS 332, at *15 (May 17, 1978). Respondents' advertising claims, including claims that the Challenged Products are "Cancer Treatments" and "Cancer Solutions," are objective product claims because the claims are stated in positive terms and are not qualified to be

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[4] Under the "falsity" theory, in order to prevail, the government must carry the burden of proving that the express or implied message conveyed by the ad is false. *Pantron I v. FTC*, 33 F.3d at 1096; *In re Thompson Medical*, 104 F.T.C. at 818-19, 1984 FTC LEXIS 6, at *379-80.

[5] Claims regarding a product's attributes, performance, or efficacy are considered "objective" claims, as opposed to mere sales "puffery," because such claims can be objectively verified. *In re Thompson Medical*, 104 F.T.C. at 788-89 n.6, 1984 FTC LEXIS 6, at *312 n.6.

statements of opinion. *See Koch v. FTC*, 206 F.2d 311, 318 (6th Cir. 1953). In addition, Respondents' testimonials constitute objective claims that the products inhibit tumors or are otherwise effective in the treatment of cancer. *See id.* Accordingly, Respondents implied that they had a reasonable basis to substantiate these claims. *See In re Thompson*, 104 F.T.C. at 813, 1984 FTC LEXIS 6, at *367. *See also* Answer ¶ 15 (admitting that Respondents relied upon a reasonable basis that substantiated the challenged representations).

In determining whether an advertiser has satisfied the reasonable basis requirement, it must be determined (1) what level of substantiation the advertiser is required to have for its advertising claims, and then (2) whether the advertiser possessed and relied on that level of substantiation. *FTC v. Pantron I*, 33 F.3d at 1096; *FTC v. QT, Inc.*, 448 F. Supp. 2d at 959. Respondents have the burden of establishing what substantiation they relied on for their product claims and Complaint Counsel has the burden of proving that Respondents' purported substantiation is inadequate. *FTC v. QT, Inc.*, 448 F. Supp. 2d at 959.

If an advertiser does not have a reasonable basis substantiating its claims, the representations are deceptive or misleading. *FTC v. Pantron I*, 33 F.3d at 1096; *FTC v. Sabal*, 32 F. Supp. 2d at 1007; *FTC v. QT, Inc.*, 448 F. Supp. 2d at 959-60. As further discussed below, the appropriate level of substantiation for health-related efficacy claims, such as those made by Respondents here, is "competent and reliable

scientific evidence." Because Respondents did not possess or rely upon such evidence, Respondents' advertising claims are misleading.

a. Competent and reliable scientific evidence is needed for health-related efficacy claims

The level of substantiation required depends on whether the advertising claims at issue are (1) establishment claims or (2) non-establishment claims. *Thompson Medical Co. v. FTC*, 791 F.2d 189, 194 (D.C. Cir. 1986). Establishment claims are those that contain representations regarding the amount of support the advertiser has for its product claims. *Id.; FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 298 (citing FTC Policy Statement on Advertising Substantiation, appended to *In re Thompson Medical*, 104 F.T.C. at 839, 1984 FTC LEXIS 6, at *434 (hereinafter "Policy on Advertising Substantiation")). "They are in effect statements 'that scientific tests establish that a product works.'" *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 298 (citing *Removatron v. FTC*, 884 F.2d at 1492 n.3). Common examples of establishment claims include statements such as "tests prove," "doctors recommend," or "studies show." *Id.* at 298-99 (citing Policy on Advertising Substantiation; *Thompson Medical Co. v. FTC*, 791 F.2d at 194) (other citations omitted). Where the challenged advertisements contain establishment claims, the Commission expects the advertiser to have at least the amount and type of substantiation it claimed to

have had. *Thompson Medical Co. v. FTC*, 791 F.2d at 194. *See Removatron v. FTC*, 884 F.2d at 1498 (holding that advertiser lacked reasonable basis for establishment claim as to product's hair removal effects, as a matter of law, because advertiser did not have any well-controlled scientific studies supporting the claim).

By contrast, a non-establishment claim is simply a claim about a product's attributes, performance, or efficacy, without indicating any particular level of support for such claim. *In re Thompson Medical*, 104 F.T.C. at 815, 1984 FTC LEXIS 6, at *370. For non-establishment claims, what constitutes sufficient substantiation may depend on multiple factors, such as the type of claim, the type of product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation that experts in the field believe is reasonable. *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 299 (citing *Removatron v. FTC*, 884 F.2d at 1492 n.3); *accord FTC v. QT, Inc.*, 448 F. Supp. 2d at 959 (citing Policy on Advertising Substantiation). In *Thompson Medical*, the Commission stated that determining the appropriate level of substantiation for non-establishment claims requires weighing the following factors: (1) the product involved; (2) the type of claim; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; and (6) the amount of substantiation experts in the field would agree is reasonable. 104 F.T.C. at 821, 1984 FTC LEXIS 6, at *387 (citing *In re Pfizer, Inc.*

81 F.T.C. 23 (1972), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986) (hereinafter the "*Pfizer* factors").

The DCO advertising at issue represents that the Challenged Products, individually or collectively, prevent, treat, or cure cancer, inhibit tumors, or ameliorate the adverse effects of chemotherapy or radiation. F. 189, 191, 193, 202, 211, 222, 224, 227, 229, 230, 232, 234, 235, 239, 245, 248, 250, 255, 257, 258, 269, 272, 275, 277-78, 280-81, 286, 288, 291, 294. The advertisements do not represent that the claims have been proven by scientific testing, except in a very few cases. *E.g.*, F. 225, 231, 247. Complaint Counsel has not alleged or argued that Respondents' advertisements constitute establishment claims. Accordingly, the claims at issue are deemed non-establishment claims, and will be evaluated as such.

As discussed below, the challenged claims made by Respondents are health-related efficacy claims. It is well established that health-related efficacy claims, including those made about dietary supplements specifically, must be substantiated by "competent and reliable scientific evidence." *FTC v. Natural Solution, Inc.*, No. CV 06-6112-JFW, 2007 U.S. Dist. LEXIS 60783, at *11-12 (C.D. Cal. Aug. 7, 2007) (requiring competent and reliable scientific evidence to substantiate claims that liquid botanical dietary supplement Knutric was a treatment to prevent and fight various forms of cancer); *FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *43-44 (requiring competent and reliable scientific evidence to substantiate claims that dietary supplements under the

brand names Thermalean, Lipodrene, and/or Spontane-ES, were effective for weight loss and sexual enhancement); *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 300, 303 (requiring competent and reliable scientific evidence to substantiate claims that dietary supplements, Coral Calcium and Supreme Greens, were effective to prevent, treat, or cure cancer); *see also FTC v. QT, Inc.*, 448 F. Supp. 2d at 961 (requiring competent and reliable scientific evidence to substantiate claims that the Q-Ray bracelet provided immediate, significant, or complete relief from various types of pain).

The foregoing authorities concluded that competent and reliable scientific evidence was the appropriate level of substantiation for health-related efficacy claims without first considering each of the *Pfizer* factors. However, to the extent specific application of the *Pfizer* factors is necessary for health-related efficacy claims, such application yields the same result: Respondents must have possessed and relied upon competent and reliable scientific evidence to substantiate the health-related efficacy claims that they made. Each of the *Pfizer* factors is considered below.

(1) The type of product

Products related to consumer health require a high level of substantiation, such as scientific tests. *In re Removatron Int'l Corp.*, No. 9200, 111 F.T.C. 206, 1985 FTC LEXIS 21, at *212 n.20 (Nov. 4, 1988),

aff'd, 884 F.2d 1489; *In re Thompson Medical*, 104 F.T.C. at 822, 1984 FTC LEXIS 6, at *388. Claims that the Challenged Products prevent, treat, or cure cancer, inhibit tumors, or ameliorate the adverse effects of radiation and chemotherapy relate to consumer health. F. 219, 236, 259, 282, 295. Accordingly, a high level of substantiation is required.

(2) The type of claim

Claims that are difficult or impossible for consumers to evaluate for themselves require a high level of substantiation, such as scientific tests. The "placebo" effect of consumer expectations when taking a purported remedy makes it difficult for consumers to verify product effectiveness for themselves. *In re Removatron*, 1985 FTC LEXIS 21, at *212 n.20; *In re Thompson Medical*, 104 F.T.C. at 822-23, 1984 FTC LEXIS 6, at *389; *FTC v. Pantron I*, 33 F.3d at 1090 n.1. In this case, for example, consumers cannot effectively determine for themselves the accuracy of the claim that BioShark inhibits tumors. Similarly, consumers reading "Tracey's" testimonial cannot evaluate whether the claimed "complete remission" of Tracey's cancer is due to her consumption of the Challenged Products or some other factor. Therefore, a high level of substantiation is required.

Respondents maintain that the challenged advertising does not state that the Challenged Products prevent, treat, or cure disease or tumors, and that Respondents' "express statements" constitute "structure/

function" claims. RPFF No. 27, 36, 42, 43. Respondents state that the phrase "structure or function," in the context of dietary supplements claims, refers to representations about a dietary supplement's effect on the structure or function of the body for maintenance of good health and nutrition. RB at 3-4 (citing the FTC's Guide, *Dietary Supplements: An Advertising Guide for Industry*, at 26 n.2). As discussed in Section III D 1, *supra*, the words used in an advertisement cannot be viewed in isolation, but must be viewed along with all the other elements of the advertisement to obtain the overall net impression. The evidence demonstrates that the overall net impression of Respondents' advertising is that the Challenged Products, individually or collectively, prevent, treat, or cure cancer, inhibit tumors, or ameliorate the adverse effects of chemotherapy or radiation. F. 189, 191, 193, 202, 211, 222, 224, 227, 229, 230, 232, 234, 235, 239, 245, 248, 250, 255, 257, 258, 269, 272, 275, 277-78, 280-81, 286, 288, 291, 294. These are health-related claims. F. 219, 236, 259, 282, 295. Therefore, Respondents' argument that they should be held to a lower standard of substantiation because they made "structure/function" claims is without merit. *See FTC v. QT, Inc.*, 448 F. Supp. 2d at 962 ("Defendants would not be required to have a gold-standard study to substantiate the Q-Ray bracelet if they did not make such a strong, medical claim. The choice belonged to Defendants.").

(3) The benefits of a truthful claim and the ease of developing substantiation for the claim

These two factors – the benefits of a truthful claim and the ease of developing substantiation for the claim – are typically considered together. The consideration of these factors seeks to ensure that the level of substantiation required is not likely to deter product development or prevent disclosure of potentially valuable information about product characteristics to consumers. *In re Removatron*, 1985 FTC LEXIS 21, at *212 n.20; *In re Thompson Medical*, 104 F.T.C. at 823-24, 1984 FTC LEXIS 6, at *391.

The fact that cancer patients could benefit from truthful claims of effective treatments is obvious. Respondents contend that developing "competent and reliable scientific evidence" is too costly for dietary supplements, and that such products should be held to a lower standard. RPFF No. 27, 36, 42, 43. However, as noted above, courts have required competent and reliable scientific evidence for claims about dietary supplements when such products are advertised to treat diseases or medical conditions. *E.g.*, *FTC v. Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *11-12; *FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *43-44; *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 300, 303. Although Respondents deny they "stated" that the Challenged Products prevent, treat, or cure cancer or tumors, the evidence shows that the advertising clearly conveyed

these claims. F. 189, 191, 193, 202, 211, 222, 224, 227, 229, 230, 232, 234, 235, 239, 245, 248, 250, 255, 257, 258, 269, 272, 275, 277-78, 280-81, 286, 288, 291, 294.

(4) The consequences of a false claim

The consequences of a false claim weigh in favor of requiring a higher level of substantiation in this case. The evidence shows that foregoing a proven cancer treatment in favor of an ineffective treatment would be injurious to a patient's health. F. 355-56. In addition, side effects and/or inappropriate dosing of a dietary supplement can cause harmful interactions that interfere with cancer treatment. F. 357-61. Furthermore, the Challenged Products are costly. F. 126-27, 135-37, 139-40, 143-44. Spending money on an ineffective remedy causes economic injury. *In re Schering Corp.*, No. 9232, 1991 FTC LEXIS 427, at *134 (Sept. 16, 1991); *In re Removatron*, 1985 FTC LEXIS 21, at *212 n.20.

(5) The amount of substantiation experts in the field believe is reasonable

Dr. Miller was the only witness in this case qualified as an expert in cancer research and cancer treatment. F. 326. His opinions, which were thorough and well-reasoned, were that competent and reliable scientific evidence is required to demonstrate that a cancer treatment is effective; that competent and

reliable scientific evidence means controlled clinical studies; that animal and in vitro studies are insufficient; and that testimonials have no scientific validity. F. 343-53. Respondents contend that the relevant field is dietary supplements, and that in this regard, Drs. Duke and LaMont are more qualified than Dr. Miller. RB at 8-9. Where, as here, a dietary supplement is claimed to have medical effects, however, it is appropriate to rely on the opinion of an expert in the medical field. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *78-79 (accepting opinion of an expert in the field of erectile dysfunction as to level of substantiation required for claims that a dietary supplement was an effective treatment).

In any event, while Drs. Duke and LaMont each opined that there was a "reasonable basis" for the statements submitted to them for evaluation, neither witness even offered an opinion as to the amount or type of substantiation that is reasonable to support a claim that the Challenged Products prevent, treat, or cure cancer. F. 338, 387-88, 395-98. Accordingly, neither witness disputed Miller's opinion that competent and reliable scientific evidence is the appropriate standard for substantiating cancer claims. *See FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *78-79. Although LaMont would include studies of animals and cell culture lines in her definition of competent and reliable scientific evidence, she also included human clinical trials in her definition. F. 344. Accordingly, the expert testimony supports holding advertising claims, such as those made by

Respondents, to the "competent and reliable scientific evidence" standard of substantiation.

b. Respondents did not possess or rely upon competent and reliable scientific evidence to substantiate their advertising claims

Respondents did not possess or rely upon competent and reliable scientific evidence to substantiate their claims that any of the Challenged Products is effective, either alone or in combination with other DCO products, in the prevention, treatment, or cure of cancer, in inhibiting tumor formation, or in ameliorating the adverse effects of radiation and chemotherapy, and in fact, no such evidence exists. F. 362-86. Claims that a dietary supplement treats a medical condition must be substantiated by clinical or scientific testing on the product itself; testing only component ingredients of the product is insufficient, unless the testing is on an exact duplicate of the product's combination of active ingredients. F. 367; *see FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *79; *FTC v. Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *14-15 n.6 (holding on summary judgment that reliance on articles on the Internet, including the Mayo Clinic, website did not constitute adequate substantiation of claims that dietary supplement prevented or treated cancer where articles only addressed potential effects of particular herbs and did not demonstrate that the formula

actually prevents or treats cancer). In the instant case, the Challenged Products were not tested to determine if they had the claimed effects. F. 308-14. Studies upon which Respondents relied evaluated isolated compounds that are present in certain of the Challenged Products and showed nonspecific immunostimulatory activities or suggested cancer preventive effects. F. 367. As in *National Urological Group* and *Natural Solution*, however, and as stated by Dr. Miller, testing only certain components of a Challenged Product does not substitute for an actual evaluation of each of the Challenged Products itself. For example, one cannot extrapolate from results of a published non-clinical study of curcumin that GDU can eliminate tumors. GDU itself, or each active ingredient in GDU, must be subjected to the same experimental conditions as those to which the curcumin was subjected. F. 367.

In addition, the materials relied upon by Respondents as substantiation consisted of author opinions and reviews of literature on the use of herbal medicines for a number of different diseases, including cancer. F. 365. Mere compilations of citations, which do not contain independent analysis or support for claims made in advertising, do not constitute substantiation. *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 300-01. Most of the studies referenced by Respondents are not peer-reviewed papers. F. 365. Respondents' substantiation materials did not include any controlled clinical trials. F. 365. Respondents' substantiation included non-clinical in vitro or animal

studies, which serve only to demonstrate potential activity and safety. F. 345, 366. Such potential activity is not sufficient substantiation for claimed anti-cancer effects. *See FTC v. Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *14-15 (holding that reliance on Internet articles which addressed potential effects of herbs in Knutric and stated that further research was required did not substantiate anti-cancer claims). Instead, competent and reliable scientific evidence to substantiate Respondents' claims requires controlled, clinical studies. F. 343-48.

Finally, Respondents' testimonials do not constitute valid scientific evidence because, among other reasons, it cannot be confirmed that the speakers had cancer, or that the speakers' reported responses were not due to other treatment modalities. *See Koch v. FTC*, 206 F.2d 311, 315-16 (6th Cir. 1953) (giving case histories no weight in verifying treatment claims, where the clinical data were based upon insufficient diagnosis or indicated use of conventional treatment along with the product). An individual's report that he or she "felt better," standing alone, does not scientifically measure response to a particular product. F. 351-53. For these and other reasons, cases consistently hold that testimonials do not constitute adequate substantiation for health-related efficacy claims in advertising. As Judge Easterbrook explained in *Federal Trade Commission v. QT, Inc.*:

> [A] person who promotes a product that contemporary technology does not understand must establish that this "magic" actually

> works. Proof is what separates an effect new to science from a swindle. . . . [D]efendants have no proof of the Q-Ray Ionized Bracelet's efficacy. The "tests" on which they relied were bunk. . . . What remain are testimonials, which are not a form of proof because most testimonials represent a logical fallacy: post hoc ergo propter hoc. (A person who experiences a reduction in pain after donning the bracelet may have enjoyed the same reduction without it. That's why the "testimonial" of someone who keeps elephants off the streets of a large city by snapping his fingers is the basis of a joke rather than proof of cause and effect.).

512 F.3d 858, 862 (7th Cir. 2008). *See also Simeon Mgmt. Corp. v. FTC*, 579 F.2d 1137, 1143-44 (9th Cir. 1978) (stating that anecdotal evidence, such as testimonials by satisfied customers, does not constitute adequate and well-controlled investigation, and therefore does not support claims that drug was effective for weight loss); *In re Warner-Lambert Co.*, No. 8891, 86 F.T.C. 1398, 1496, 1975 FTC LEXIS 12, at *213 (Dec. 9, 1975) ("Since there may be a divergence between what the user thinks the product will do for him and what the product actually does (or does not do), evidence of consumer beliefs has little probative value for determining whether" a product works in the manner claimed), *aff'd*, 562 F.2d 749 (D.C. Cir. 1977).

Respondents argue that the literature upon which they relied constitutes "reasonable" support for

their "express statements" which they contend are "structure/function" claims. RFF Nos. 26, 40; RCOL Nos. 18, 19. As discussed in Section III E 1-5 *supra*, the overall net impression of the DCO advertising is that each of the Challenged Products, either alone or in combination with other DCO products, is effective in the prevention, treatment, or cure of cancer, in inhibiting tumor formation, or in ameliorating the adverse effects of radiation and chemotherapy. F. 189, 191, 193, 202, 211, 222, 224, 227, 229, 230, 232, 234, 235, 239, 245, 248, 250, 255, 257, 258, 269, 272, 275, 277-78, 280-81, 286, 288, 291, 294. The fact that there may have been some basis to support the "express" words of product descriptions, taken out of context, is immaterial because Respondents had no competent and reliable scientific evidence to substantiate the overall net impression conveyed by their advertisements. *See FTC v. Bronson Partners*, 564 F. Supp. 2d at 133-34 (holding that expert report that included conclusions that Chinese Diet Tea "could lead to weight reduction," "can be a useful part of a weight reduction program," and "can help reduce fat absorption," while supporting the generalized notion that the product could be a useful part of a weight reduction program, did not support advertising claims that the product will lead to rapid and substantial weight loss).

It bears mentioning that Respondents' strategy throughout this case, despite clear and well-established law, has been to ignore each component of their advertising *except* the "express" words of their product

descriptions, as though those statements stand alone. Following this strategy, Respondents did not seek, nor did any of their proffered experts offer, an opinion as to whether there was competent and reliable scientific evidence to support the claims that were alleged in the Complaint. F. 339-40, 387-89, 397, 399-400, 405, 408-09, 418, 420-21, 422, 424-25. Respondents' proffered experts were not asked to review, and none of them did review, any of the DCO advertising at issue. F. 338, 387, 395-96, 404, 410, 418, 422. None of Respondents' proffered experts, with the possible exception of Roy, opined as to what level of substantiation is necessary or appropriate for claims that a dietary supplement prevents, treats, or cures cancer. F. 387-88, 397-98, 405-07, 418-19, 422-23. None of Respondents' proffered experts had any expertise in treating cancer, or in testing the efficacy of proposed cancer treatments. F. 330-37, 414-17. The result of Respondents' strategy is that none of Respondents' proffered experts offered any opinions on any material, contested issue in the case, and the opinions that Respondents' proffered experts did offer are entitled to little, if any, weight.

c. Respondents' claims are deceptive or misleading

Complaint Counsel can show that a representation is deceptive or misleading by showing that the advertiser lacked a reasonable basis for asserting that the message was true. *FTC v. Pantron I*, 33 F.3d at 1096; *FTC v. Sabal*, 32 F. Supp. 2d at 1007; *FTC*

v. QT, Inc., 448 F. Supp. 2d at 959-60. Complaint Counsel has demonstrated that Respondents lacked a reasonable basis for their claims that the Challenged Products, individually or collectively, prevent, treat, or cure cancer or inhibit tumors, or ameliorate the adverse effects of chemotherapy and radiation. Accordingly, Complaint Counsel has demonstrated that Respondents' claims are deceptive or misleading.

3. Respondents' advertising claims are material

"A claim is considered material if it 'involves information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding a product.'" *Kraft v. FTC*, 970 F.2d at 322 (citations omitted). Health-related efficacy claims are consistently held to involve information that is important to consumers. *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 299-300; *FTC v. QT, Inc.*, 448 F. Supp. 2d at 966; *accord FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *45-46. Furthermore, the Commission is entitled to presume materiality for claims involving health concerns. *Kraft v. FTC*, 970 F.2d at 323. *Accord Novartis Corp. v. FTC*, 223 F.3d 783, 786 (D.C. Cir. 2000) (noting that information has been presumed material where it "concerns the purpose, safety, efficacy, or cost of the product or service") (quoting FTC Policy Statement on Deception, appended to *In re Cliffdale Assocs.*, 103 F.T.C. 110, 182, 1984 FTC LEXIS 71, at *189 (Mar. 23, 1984)); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 966. The presumption may be

rebutted with extrinsic evidence indicating that the claims are not material. *FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *81.

Respondents' advertising claims that the Challenged Products, individually or collectively, prevent, treat, or cure cancer or inhibit tumors, or ameliorate the adverse effects of chemotherapy and radiation unquestionably relate to health concerns. F. 219, 236, 259, 282, 295. Claims that relate to health concerns are material. *FTC v. Direct Marketing Concepts*, 569 F. Supp. 2d at 299-300 (holding that claims that dietary supplements could prevent or treat cancer and other diseases were health-related efficacy claims which were "clearly material"); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 966 (stating that claims that the Q-Ray bracelet provides immediate, significant, or complete relief from various types of pain were "[w]ithout question" medical, health-related claims that were material to consumers); *FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *46 (applying presumption of materiality to claims that dietary supplements were effective to treat weight loss and sexual dysfunction). Therefore, Respondents' claims are clearly material. In addition, Respondents did not make any argument, or attempt to introduce any evidence, that their claims are not material to consumers. Accordingly, Respondents' claims are deemed material.

E. Respondents' Defenses

Respondents have raised numerous defenses. Some of these defenses have been addressed in other sections of this Initial Decision.[6] Only a few of Respondents' remaining defenses merit discussion, and these are addressed below. Regardless of whether a defense is specifically addressed in this Initial Decision, each of Respondents' defenses has been fully considered, and rejected as being without sufficient basis in fact and/or law.

1. Claims regarding insufficient proof

a. Proof of unfair trade practices under Section 5(n) of the Act

Respondents argue that Complaint Counsel must prove that Respondents' acts or practices are not only deceptive, but also "unfair," as defined under Section 5(n) of the FTC Act. That Section provides:

> (n) Definition of unfair acts or practices. The Commission shall have no authority under this section or section 18 [15 U.S.C. § 57a] to declare unlawful an act or practice on the grounds that such act or practice is unfair unless the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by

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[6] *See, e.g.*, Sections III B (jurisdiction); III D 1 (interpretation of advertisements); III D 1 f (disclaimers); III D 1 g (extrinsic evidence); III D 2 a (level of substantiation).

> consumers themselves and not outweighed by countervailing benefits to consumers or to competition. In determining whether an act or practice is unfair, the Commission may consider established public policies as evidence to be considered with all other evidence. Such public policy considerations may not serve as a primary basis for such determination.

15 U.S.C. § 45(n).

Respondents' argument fails. Respondents cite no authority for their contention that the evidence must show that deceptive trade practices are also unfair because of substantial consumer injury. Moreover, the law is contrary to Respondents' position. It is well established that proof of deception does not require proof of actual consumer injury. *FTC v. Direct Marketing Concepts,* 569 F. Supp. 2d at 297; *In re Kraft,* 1991 FTC LEXIS 38, at *38. This is because misrepresentations harm consumer choice, and in this regard, injure both consumers and competition. *In re Novartis Corp.,* 1999 FTC LEXIS 63, at *26. Accordingly, the harm resulting from a deceptive practice renders such practice "unfair" as well. *In re Southwest Sunsites, Inc.,* No. 9134, 105 F.T.C. 7, 1980 FTC LEXIS 86, at *338 n.81 (Jan. 15, 1985). Indeed, the provisions of Section 12(b) of the FTC Act recognize this principle, by providing that false advertising is, by definition, an "unfair or deceptive" act or practice within the meaning of Section 5 of the FTC Act. 15 U.S.C. § 52(b). Therefore, there is no legal or logical

reason to require additional, independent proof of unfairness under Section 5(n), 15 U.S.C. § 45(n).

b. Proof of inadequate substantiation

(1) Requirement of placebo-controlled, double-blind studies

Respondents assert that placebo-controlled, double-blind studies are not required for adequate substantiation under the FTC Act. RB at 2-3 (citing *FTC v. QT, Inc.*, 512 F.3d 858). Respondents correctly note that the court in *Federal Trade Commission v. QT, Inc.* stated: "Nothing in the Federal Trade Commission Act . . . requires placebo-controlled, double-blind studies. . . . Placebo-controlled, double-blind testing is not a legal requirement for consumer products." 512 F.3d at 861. However, Respondents ignore the fact that the appellate court affirmed the district court's holdings that substantiation for health-related efficacy claims must be based on competent and reliable scientific evidence, and that the studies upon which defendants relied were inadequate under that standard. *Id.* at 862. Moreover, the appellate court held that its conclusion regarding double-blind, placebo-controlled studies was of no help to the defendants because, as the district court had found after exhaustive analysis of the defendants' studies, "defendants ha[d] no proof" to support their advertising claims. *Id.*

In the instant case as well, the language in *Federal Trade Commission v. QT, Inc.* regarding placebo-controlled, double-blind studies does not help

Respondents because, as discussed in Section III D 2 *supra*, Respondents did not possess or rely upon any adequate substantiation for their claims that the Challenged Products prevent, treat, or cure cancer. Respondents had no studies whatsoever of the effects of the Challenged Products themselves. F. 308-14. Respondents' substantiation materials included studies on isolated compounds that are present in some of the Challenged Products, rather than studies of the exact combinations of constituent ingredients in the Challenged Products. F. 367. Respondents' own proffered expert, Dr. LaMont, admitted that because the products have not been tested, the effectiveness of BioShark, 7 Herb Formula, GDU, and BioMixx to prevent, treat, or cure cancer is not known. F. 364. Most of the substantiation materials upon which Respondents relied were not peer-reviewed papers. F. 365. Respondents' substantiation materials did not include controlled clinical human trials. F. 365. Respondents' substantiation materials included author opinions and reviews of literature on the use of herbal medicines. F. 365. Many of the studies cited in Respondents' reference materials were in vitro or animal studies. F. 366. Ultimately, like the defendants in *QT, Inc.*, Respondents here relied on testimonials (F. 316), "which are not a form of proof." 512 F.3d at 862.

(2) Substantiation for "structure-function" claims under DSHEA

Respondents further contend that a high level of substantiation, such as placebo-controlled, double-blind

studies, is not required because, according to Respondents, Respondents made "structure-function" claims under the Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4325 (DSHEA). RB at 3, 7-8. Respondents cite 21 U.S.C. § 343(r)(6)(A), which relaxes certain DSHEA misbranding rules for statements on labels that "describe . . . the role of a nutrient or dietary ingredient intended to affect the structure or function in humans." In this case, the evidence demonstrates that Respondents made health-related efficacy claims. *See supra* Section III D 1-2. Such claims would not be deemed "structure-function" claims under DSHEA, even according to the cases cited by Respondents. *See Pearson v. Shalala*, 164 F.3d 650, 652 (D.C. Cir. 1999) (stating that claims that consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers, consumption of fiber may reduce the risk of colorectal cancer, consumption of omega-3 fatty acids may reduce the risk of coronary heart disease, and 8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form constitute "health claims" under FDA regulations); *United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 568 (D.N.J. 2004) (holding that claims that shark cartilage products were an effective treatment for cancer and HIV/AIDS were not structure-function claims). In any event, this case does not present issues relating to labeling under DSHEA, but advertising and unfair acts or practices under the FTC Act. Complaint ¶¶ 7-14, 16; 15 U.S.C. §§ 45(a), 52.

(3) FTC Guidelines for Dietary Supplement Advertising

Next, Respondents argue that Complaint Counsel ignored FTC guidelines regarding the advertising of dietary supplements. RB at 4, 8 (citing the FTC's Guide, *Dietary Supplements: An Advertising Guide for Industry*, available at http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.shtm (hereinafter, "Guidelines")). Respondents contend that the Guidelines state that: (1) the evaluation of substantiation for dietary supplement claims must be flexible to ensure consumers have access to information about emerging areas of science; (2) there is no requirement that dietary supplement claims be supported by a specific number of studies; and (3) research concerning the biological mechanism underlying the claimed action of a dietary supplement is acceptable substantiation for dietary supplement claims. RB at 4, 8.

Respondents misconstrue the Guidelines. The first statement from the Guidelines that Respondents contend was ignored introduces a discussion of the five factors relevant in evaluating substantiation, which are the same as the five *Pfizer* factors. *See* Guidelines at 8-9; *In re Thompson Medical*, 104 F.T.C. 648, 821, 1984 FTC LEXIS 6, at *387. The *Pfizer* factors were considered and applied in this case. *See supra* Section III D 2 a. The second statement from the Guidelines, to which Respondents referred, is preceded by important qualifying statements, which Respondents ignore, including that "the [amount and type of] evidence needed depends on the nature of the

claim," that "all competent and reliable scientific research" should be considered, and that "the quality of studies [is] more important than quantity." Guidelines at 10. The nature of Respondents' claims was thoroughly considered in determining the level of substantiation required. *See supra* Section III D 1-2 a. The quality of Respondents' substantiation was fully evaluated and determined to not constitute competent and reliable scientific evidence. *See supra* Section III D 2 b. Finally, regarding Respondents' third statement, the Guidelines simply do not state that "research concerning the biological mechanism underlying the claimed action of a dietary supplement is acceptable substantiation for dietary supplement claims." The Guidelines state: "When a clinical trial is not possible (e.g., in the case of a relationship between a nutrient and a condition that may take decades to develop), *epidemiologic evidence may be* an acceptable substitute for clinical data, especially when supported by other evidence, such as research explaining the biological mechanism underlying the claimed effect." Guidelines at 10 (emphasis added). To the extent Respondents' substantiation materials included any "research explaining the biological mechanism" of the Challenged Products, it was determined that such materials did not constitute adequate substantiation for the claim that the Challenged Products prevent, treat, or cure cancer. *See supra* Section III D 2 b.

2. Due process claim

Although Respondents' due process claim is difficult to discern, it appears to be based upon what Respondents contend is a lack of evidence. Respondents assert that: Under DSHEA, dietary supplements must be proved harmful; there is no evidence of unfairness or consumer injury; and extrinsic evidence is necessary to determine the overall net impression of their advertising. RB at 10-11. To find liability without such evidence, according to Respondents, violates their procedural due process rights, under *Mathews v. Eldridge,* 424 U.S. 319 (1976) and *Stanley v. Illinois,* 405 U.S. 645 (1972). Neither cited opinion has any bearing on this case legally or factually. Moreover, each alleged evidentiary deficiency has been proved erroneous. As noted in *supra* Sections III D 1 g and III E 1 a-b, DSHEA law does not govern this deceptive advertising case, consumer injury is not an element of proof in a deceptive advertising case, unfairness is not an element of proof in a deceptive advertising case, and extrinsic evidence is not necessary to determine the overall net impression of advertisements where, as here, the meaning is sufficiently clear on the face of the advertisements. Accordingly, Respondents' due process argument has no merit.

3. *United States v. Johnson*

Respondents rely on the near-century-old case of *United States v. Johnson,* 221 U.S. 488 (1911) to argue that unsubstantiated claims regarding product

effectiveness are not unlawful because such claims are matters of opinion, not fact. *See, e.g.*, Respondents' Motion to Dismiss, Jan. 11, 2009, at 6-8. *Johnson* involved the question of whether medicine bottles, whose labels contained false and misleading representations that the medicine was effective in curing cancer, were "misbranded" within the meaning of Section 8 of the Food and Drug Act of 1906. 221 U.S. at 495-97. The Court held that the Act was not intended to cover all possible false or misleading statements regarding medicine, but only those related to the identity of the contents of the medicine. *Id.* On its face, *Johnson* has no application to this case. In addition, Congress implicitly overruled *Johnson* by amending the Food and Drug Act to expressly include claims regarding curative effectiveness. Act of June 30, 1906, as amended, 37 Stat. 416 (1912). Finally, as noted in Section III D 2 *supra*, Respondents' advertising claims, including claims that the Challenged Products are "Cancer Treatments" and "Cancer Solutions," are stated in positive terms, and not qualified by opinion. *See Koch v. FTC*, 206 F.2d at 318 (holding that representations concerning the therapeutic value of certain medicinal preparations were within jurisdiction of FTC). Respondents' claims are representations of fact because they are subject to objective verification. *See In re Thompson Medical*, 104 F.T.C. 648, 788-89 n.6, 1984 FTC LEXIS 6, at *312 n.6 (stating that claims that can be objectively verified do not constitute mere "puffery"). Thus, *Johnson* does not support Respondents' position.

4. First Amendment defense

Respondents assert that their statements about the Challenged Products reflect both their religious view of life grounded in the Christian Bible and their political beliefs concerning allopathic drugs and pharmaceutical companies. RB at 12-13. Thus, Respondents maintain, their statements about the Challenged Products constitute religious and political speech protected by the First Amendment to the U.S. Constitution. RB at 12-13. Respondents further argue that even if their statements are found to be commercial speech, they are protected by the First Amendment. RB at 13. Respondents also assert that the FTC has the burden of showing that Respondents' statements are misleading and the burden of proving that suppression of those statements is necessary to achieve a substantial government interest. RB at 16. In addition, Respondents assert that the First Amendment doctrine of prior restraint would prohibit an FTC order enjoining Respondents' representations. RB at 14.

Complaint Counsel asserts that Respondents' representations constitute commercial speech. CCB at 32. Complaint Counsel further states that the evidence demonstrates that the challenged advertisements and promotional materials, which are broadly disseminated on the Internet to draw consumers, contain little or no religious commentary. CCB at 32-33. Complaint Counsel also contends that this commercial speech is deceptive and, therefore, not protected by the First Amendment. CCB at 34-35. In addition,

Complaint Counsel maintains that the FTC's action does not constitute a prior restraint. CCB at 35.

Supreme Court decisions "have recognized 'the "common-sense" distinction between speech proposing a commercial transaction, which occurs in an area traditionally subject to government regulation, and other varieties of speech.'" *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 64 (1983) (quoting *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 455-56 (1978)). Thus, the Supreme Court has held that the Constitution accords less protection to commercial speech than to other constitutionally safeguarded forms of expression. *Id.* at 64-65 (citing *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York*, 447 U.S. 557, 562-563 (1980); *Virginia Pharm. Bd. v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771-72 n.24 (1976)).

"[A]s a general matter, 'the First Amendment means that government has no power to restrict expression because of its message, its ideas, its subject matter, or its content.'" *Id.* at 65 (quoting *Police Dep't of Chicago v. Mosley*, 408 U.S. 92, 95 (1972)). Thus, with respect to noncommercial speech, the Supreme Court has "sustained content-based restrictions only in the most extraordinary circumstances." *Id.* "By contrast, regulation of commercial speech based on content is less problematic." *Id.* "In light of the greater potential for deception or confusion in the context of certain advertising messages, content-based restrictions on commercial speech may be permissible."

Id. (citing *In re R. M. J.*, 455 U.S. 191, 200 (1982); *Friedman v. Rogers*, 440 U.S. 1 (1979)).

"Because the degree of protection afforded by the First Amendment depends on whether the activity sought to be regulated constitutes commercial or noncommercial speech," *id.*, a determination must first be made as to whether Respondents' challenged representations constitute commercial speech. Once it is determined that the language at issue is commercial speech, case law makes clear that misleading or deceptive commercial speech is not protected by the First Amendment.

a. Respondents' statements constitute commercial speech

The determination of whether speech is commercial speech "rests heavily on 'the common sense distinction between speech proposing a commercial transaction . . . and other varieties of speech.'" *Zauderer v. Office of Disciplinary Council*, 471 U.S. 626, 637-38 (1985) (citations omitted); *In re R.J. Reynolds Tobacco Co.*, No. 9206, 111 F.T.C. 539, 1988 FTC LEXIS 9, at *9 (Mar. 4, 1988) ("The Supreme Court has referred to the 'core notion' of commercial speech as speech which proposes a commercial transaction.") (citations omitted). As a result, the determining factor is whether the speech at issue "propose[s] a commercial transaction." *Board of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 473-74 (1989).

Whether the speaker has an economic motivation for the speech is germane to the issue of whether the speech is commercial. *In re Primus,* 436 U.S. 412, 438 n.32 (1978) (stating that the line between commercial and noncommercial speech is "based in part on the motive of the speaker"); *Bolger,* 463 U.S. at 66. Another consideration is whether the statements refer to specific products. *Bolger,* 463 U.S. at 66; *In re R.J. Reynolds,* 1988 FTC LEXIS 9, at *14 ("[I]nformation about attributes of a product or service offered for sale, such as type, price, or quality, is also indicative of commercial speech.") (citing *Friedman v. Rogers,* 440 U.S. 1, 11 (1979)). The Federal Trade Commission has specifically stated: "[I]nformation about health effects associated with the use of a product can properly be classified as commercial speech." *In re R.J. Reynolds,* 1988 FTC LEXIS 9, at *14 (citing *Bolger,* 463 U.S. at 66-67; *National Comm'n on Egg Nutrition v. FTC,* 570 F.2d 157, 163 (7th Cir. 1977)).

In this case, the evidence very clearly shows that Respondents' speech is economically motivated and proposes a commercial transaction by urging consumers to purchase specific products. Respondent James Feijo conceded at trial that the DCO Website constitutes advertising. F. 161. Moreover, the content of Respondents' advertising promotes specific products and their attributes, and urges consumers to purchase those products. For example, in the BioMolecular Nutrition Product Catalog, Respondents list and describe the Challenged Products and state, "Call Toll

FREE 1-800-504-5511 or shop online at www.daniel chapterone.com." F. 91. There is no mention of a DCO ministry in the BioMolecular Nutrition Product Catalog. F. 93. In the exhibits attached to the Complaint, and admitted into evidence, Respondents clearly propose commercial transactions. F. 179-80 (webpage from the DCO Website, entitled "Cancer News," which contains a picture of 7 Herb Formula and states regarding the Challenged Products as a group: "If you suffer from any type of cancer, Daniel Chapter One suggests taking 7*Herb Formula™, Bio*Shark™, BioMixx™, GDU™." Immediately following this text is a prominent picture of bottles of BioMixx, 7 Herb Formula, Bio*Shark, and GDU, and adjacent to that is a statement in bold type, "Daniel Chapter One's Cancer solutions," and text that states: "To Buy the products click here. How to fight cancer is your choice!") (emphasis omitted); F. 220-21 (printout of the webpage for BioShark on the DCO Website, with a heading in bold type, "Immune Boosters," a picture of bottles of BioShark, and a shopping cart icon with the instruction, "BUY NOW!") (emphasis omitted); F. 262-63 (webpage for GDU on the DCO Website, which begins with a heading in bold type, "Immune Boosters," depicts bottles of GDU, with text that includes "[t]his formula also helps to relieve pain and heal inflammation," and provides a link to "buy now."). Further, Respondents' representations convey information about the health effects that are purportedly associated with the use of their products. *See supra* Section III D 1-2. *E.g.*, F. 180 (DCO Website stating:

"If you suffer from any type of cancer, Daniel Chapter One suggests taking [the Challenged Products]").

In addition to evaluating the content of the speech, the Supreme Court has found that the means used to publish speech is relevant to how speech should be classified. *In re R.J. Reynolds,* 1988 FTC LEXIS 9, at *15. For example, the Court has recognized that commercial speech frequently takes the form of paid-for advertising. *Id.* (citing *Bolger,* 463 U.S. at 66; *Bates v. State Bar of Ariz.,* 433 U.S. 350, 363-64 (1977); *Virginia State Board of Pharmacy,* 425 U.S. at 761). Respondents operate the DCO Website, www.danielchapterone.com, and the websites www.dc1pages.com, www.dc1store.com, www.7herbformula.com, and www.gdu2000.com, through which they accept consumers' orders. F. 103-04. Respondents have spent money to have the DCO websites and written publications created and for cable advertising services. F. 159-60.

Given the foregoing, the religious or political views, upon which Respondents' advertising was assertedly based, do not convert Respondents' commercial speech to constitutionally protected religious or political speech. In *Bolger,* the Supreme Court found that mailings constituted "commercial speech notwithstanding the fact that they contain discussions of important public issues such as venereal disease and family planning." *Bolger,* 463 U.S. at 67-68. "We have made clear that advertising which 'links a product to a current public debate' is not thereby entitled to the constitutional protection afforded

noncommercial speech." *Id.* at 68 (quoting *Central Hudson,* 447 U.S. at 563 n.5). The Supreme Court further held: "A company has the full panoply of protections available to its direct comments on public issues, so there is no reason for providing similar constitutional protection when such statements are made in the context of commercial transactions. Advertisers should not be permitted to immunize false or misleading product information from government regulation simply by including references to public issues." *Id. See also Central Hudson,* 447 U.S. at 563 (stating that failing to honor distinction between commercial and noncommercial speech "could invite dilution, simply by a leveling process, of the force of the [First] Amendment's guarantee with respect to the latter kind of speech") (quoting *Ohralik v. Ohio State Bar Ass'n,* 436 U.S. at 456). Thus, even though Respondents assert that their representations are based on their religious view of life grounded in the Christian Bible and positioned as a political argument against drugs and pharmaceutical companies, RB at 12-13, it is clear from the foregoing examples that Respondents' speech seeks to promote sales of the Challenged Products. Accordingly, Respondents' challenged representations constitute commercial speech.

b. Misleading commercial speech may be prohibited

For commercial speech to receive the protections of the First Amendment, "it at least must concern

lawful activity and not be misleading." *Central Hudson*, 447 U.S. at 566. As the Supreme Court has explained:

> The First Amendment's concern for commercial speech is based on the informational function of advertising. Consequently, there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity. The government may ban forms of communication more likely to deceive the public than to inform it, or commercial speech related to illegal activity.

Id. at 563-64. It is well settled that "[t]he States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading." *Zauderer*, 471 U.S. at 638; *In re R. M. J.*, 455 U.S. at 203 (noting that the government may prohibit false or misleading commercial advertising entirely).

Restrictions on deceptive advertising of food and drugs have repeatedly been upheld against First Amendment challenges. *Association of Nat'l Advertisers v. Lungren*, 44 F.3d 726, 734 n.3 (9th Cir. 1994) (citing *Kraft v. FTC*, 970 F.2d at 324-26 (upholding FTC ban on deceptive claims about the calcium content of processed cheese products); *Bristol-Myers Co. v. FTC*, 738 F.2d 554, 562 (2d Cir. 1984) (upholding FTC prohibitions on certain types of advertising claims about analgesics)). *See also FTC v. National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at

*29-30 (citing *Bristol-Myers v. FTC*, 738 F.2d at 562 ("deceptive advertising enjoys no constitutional protection")). "Even in the absence of a finding of actual deception, agencies may properly regulate speech that is merely potentially deceptive." *Bristol-Meyers v. FTC*, 738 F.2d at 562 (citing *Friedman v. Rogers*, 440 U.S. 1, 15 (1979)). Respondents' representations have been found to lack adequate substantiation and therefore have been determined to be deceptive or misleading. *See supra* Section III D 2. Accordingly, the deceptive commercial speech at issue in this case is not protected by the First Amendment.

c. *Central Hudson* does not apply

Respondents argue that even if their statements are found to be commercial speech, they are protected by the First Amendment under *Central Hudson*. RB at 13, 16, 22. In *Central Hudson*, the Supreme Court set out the standards applicable to governmental restrictions on commercial speech: The State must assert a substantial interest to be achieved by restrictions on commercial speech; the regulatory technique must be in proportion to that interest; and the limitation on expression must be designed carefully to achieve the State's goal. *Central Hudson*, 447 U.S. at 564. The *Central Hudson* test, however, is applied "if the communication is neither misleading nor related to unlawful activity." *Id.*; *Grolier Inc. v. FTC*, 699 F.2d 983, 988 (9th Cir. 1983). Where, as here, Respondents' practices are unlawful or misleading, First Amendment protections do not apply.

Grolier v. FTC, 699 F.2d at 988; *National Urological Group*, 2008 U.S. Dist. LEXIS 44145, at *30 (stating that *Central Hudson* test did not apply to the FTC deceptive advertising case before the court). Therefore, the *Central Hudson* test does not apply to this deceptive advertising case.

d. Other cases relied upon by Respondents do not apply

Respondents cite numerous First Amendment commercial speech cases involving advertisements for accountants and attorneys to show how the Supreme Court "restated its *Central Hudson* test." RB at 16-18. Respondents' reliance upon these cases is misplaced. The accountant and attorney advertisement cases that Respondents cite all involve commercial speech that was not misleading or that did not involve unlawful activity. *See Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 620-24 (1995) (holding that the Florida Bar Rules prohibiting personal injury lawyers from sending targeted direct-mail solicitations to victims and their relatives for thirty days following an accident or disaster did not violate the First Amendment); *Ibanez v. Fla. Dep't of Bus. and Prof'l Regulation Bd. of Accountancy*, 512 U.S. 136, 139, 142 (1994) (concluding that the Board's decision censoring petitioner was incompatible with the First Amendment, but recognizing that "false, deceptive, or misleading commercial speech may be banned"); *Edenfield v. Fane*, 507 U.S. 761, 765-66 (1993) (holding that Florida's rule prohibiting certified public accountants from engaging in

"direct, in-person, uninvited solicitation" is inconsistent with the free speech guarantees of the First Amendment when the speech involved is truthful and nondeceptive); *Peel v. Attorney Registration and Disciplinary Comm'n of Ill.*, 496 U.S. 91, 100, 110-11 (1990) (stating that an attorney's letterhead was not actually or inherently misleading, because a lawyer has a constitutional right, under the standards applicable to commercial speech, to advertise his or her certification, but stating that "[m]isleading advertising may be prohibited entirely"); *In re R. M. J.*, 455 U.S. at 206-07 (stating that there is "no finding that appellant's speech was misleading" but noting that "the States retain the authority to regulate advertising that is inherently misleading or that has proved to be misleading in practice"). In the instant case, Respondents' challenged speech is misleading and unlawful. Accordingly, the commercial speech cases upon which Respondents rely are inapposite.

e. The FTC's action does not constitute a prior restraint

Respondents have asserted that this administrative proceeding and the issuance of a cease and desist order impose a prior restraint, in violation of their First Amendment rights, because there has been no proof that any consumer was actually misled or "physically harmed." RRB at 13-15. Respondents misapply the concept of "prior restraint." "The term 'prior restraint' is used 'to describe administrative and judicial orders forbidding certain communications when

issued in advance of the time that such communications are to occur.'" *Alexander v. United States*, 509 U.S. 544, 550 (1993) (citations omitted). Courts have consistently held that a FTC cease and desist order prohibiting representations about performance of products without substantiation is not an unconstitutional "prior restraint," but a reasonable sanction, imposed after a hearing establishes a violation of the FTC Act. *E.g., Jay Norris, Inc. v. FTC*, 598 F.2d 1244, 1252 (2d Cir. 1979) ("[B]ecause the FTC here imposes the requirement of prior substantiation as a reasonable remedy for past violations of the Act, there is no unconstitutional prior restraint of petitioners' protected speech."); *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 399 (9th Cir. 1982) ("[T]he Commission may require prior reasonable substantiation of product performance claims after finding violations of the Act, without offending the [F]irst [A]mendment."). Thus, the cease and desist order entered here, only after an administrative trial where the evidence conclusively showed that Respondents' advertising was misleading, does not constitute a prior restraint.

The defenses advanced by Respondents are without merit. Accordingly, they do not provide a basis for holding that Respondents are not liable for the proven violations of the FTC Act.

F. Summary of Liability

The Complaint charges that the acts and practices of Respondents, as alleged in the Complaint,

constitute deceptive advertising in violation of Sections 5(a) and 12 of the FTC Act. Complaint Counsel has presented reliable, probative, and substantial evidence in support of the Complaint's charges. The defenses raised by Respondents have been considered and rejected. Accordingly, Respondents DCO and James Feijo are hereby found liable for violating Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a), 52.

G. Remedy

On determination that a challenged act or practice is prohibited by Section 5 of the FTC Act, the appropriate remedy is an order requiring respondents to cease and desist from such act or practice. 15 U.S.C. § 45(b); *FTC v. National Lead Co.*, 352 U.S. 419, 428 (1957). Courts have long recognized that the Commission has considerable discretion in fashioning an appropriate remedial order, subject to the constraint that the order must bear a reasonable relationship to the unlawful acts or practices. *See, e.g., FTC v. Colgate-Palmolive Co.*, 380 U.S. at 394-95; *FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952); *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 612-13 (1946).

As held above, DCO is liable for the violations of the FTC Act alleged in the Complaint. Further, as set forth below, James Feijo is individually liable and an Order against him, as well as DCO, is appropriate. The Order attached herewith is reasonably related to the proven violations.

1. Individual liability

When both a corporation and an individual are named in the complaint, to obtain a cease and desist order against the individual, Complaint Counsel must prove violations of the FTC Act by the corporation and that the individual either directly participated in the acts at issue or had authority to control them. *FTC v. Amy Travel Serv., Inc.*, 875 F.2d at 573; *see also FTC v. Standard Educ. Soc'y*, 302 U.S. 112, 119-20 (1937) (finding it proper for Commission to include individuals who were in charge and control of the affairs of respondent corporations in the Commission's cease and desist order). As summarized in Section III F, DCO violated the FTC Act. As summarized in Section III B 6, Respondent James Feijo both participated directly in and had the authority to control and, in fact, did direct and control the deceptive representations at issue. Accordingly, James Feijo is individually liable for acts or practices of Respondent DCO that violate Sections 5 and 12 of the FTC Act, and the entry of a cease and desist order against James Feijo is appropriate.

2. Specific provisions of the Order

The Order attached to this Initial Decision is substantially the same as the proposed order that accompanied the Complaint in this matter. The only substantive change in this Order from the proposed order attached to the Complaint is to the language in the letter, appended as Attachment A to the Order,

that Respondents are required by this Order to send to consumers of the Challenged Products. That change is discussed below.

As a result of the Findings and Conclusions in this case, the Order prohibits Respondents from making the types of misrepresentations challenged in the Complaint. The Order also provides fencing-in relief, requiring Respondents to possess competent and reliable scientific evidence supporting certain future claims about any dietary supplement, food, drug, or other health-related product, service, or program. These provisions are discussed below. In addition, the Order contains standard provisions regarding record-keeping, dissemination of the order to officers and employees, prior notification of corporate changes, filing compliance reports, and sunsetting of the Order.

a. Competent and reliable scientific evidence requirement

The Order prohibits Respondents from making representations that any health-related program, service, or product prevents, treats, or cures, or assists in the prevention, treatment, or cure of any type of tumor or cancer, unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation. "Competent and reliable scientific evidence" is defined in the Order to mean "tests, analyses, research,

studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."

Commission orders requiring respondents to have competent and reliable scientific evidence, as defined in this Order, that is based on the expertise of professionals in the area and that has been conducted and evaluated by persons qualified to do so, are typical and have been consistently upheld. *E.g., In re Telebrands,* 140 F.T.C. at 347, *aff'd,* 457 F.3d 354; *In re Kraft,* 114 F.T.C. at 149, *aff'd,* 970 F.2d 311 (7th Cir. 1992). *See also In re Thompson Medical,* 104 F.T.C. at 844, *aff'd,* 791 F.2d at 192 (upholding order requiring respondents to possess and rely upon a reasonable basis consisting of competent and reliable scientific or medical evidence to substantiate certain representations, and defining "'competent and reliable scientific evidence' [to] include at least two adequate and well-controlled, double-blinded clinical studies . . . by persons . . . qualified by training and experience to conduct such studies"); *In re Removatron,* 1985 FTC LEXIS 21, at *167, *aff'd,* 884 F.2d at 1498 (upholding order requiring respondents to possess and rely upon competent and reliable scientific evidence to substantiate representations and defining "'competent and reliable scientific evidence' . . . as adequate and well-controlled, double-blind clinical testing conforming to acceptable designs

and protocols and conducted by a person or persons qualified by training and experience to conduct such testing").

b. Fencing-in provision

The Order entered herewith prohibits Respondents from making certain representations not only as to the Challenged Products, but also as to any substantially similar health-related program, service, or product, or any other Covered Product or Service. "Covered Product or Service" is defined in the Order to mean any dietary supplement, food, drug, or other health-related product, service, or program, including, but not limited to, BioShark, 7 Herb Formula, GDU, and BioMixx. Thus, the Order, by prohibiting Respondents from engaging in deceptive practices concerning products in addition to the Challenged Products, provides "fencing-in" relief.

"Fencing-in" relief refers to provisions in an FTC order that are broader than the conduct that is declared unlawful and may extend to multiple products. *Telebrands Corp. v. FTC,* 457 F.2d 354, 357 n.5 (4th Cir. 2006) (citing *In re Telebrands,* 140 F.T.C. at 281 n.3); *American Home Prods. v. FTC,* 695 F.2d at 705; *Kraft v. FTC,* 970 F.2d at 326 (citing *FTC v. Colgate-Palmolive,* 380 U.S. at 395; *Sears v. FTC,* 676 F.2d at 391-92). "Fencing-in remedies are designed to prevent future unlawful conduct." *Telebrands,* 457 F.2d at 357 n.5 (citing *In re Telebrands,* 140 F.T.C. at 281 n.3).

"Such an order must be sufficiently clear that it is comprehensible to the violator, and must be 'reasonably related' to a violation of the Act." *Kraft,* 970 F.2d at 326 (citation omitted). In determining whether a broad fencing-in order bears a "reasonable relationship" to a violation of the FTC Act, Courts and the Commission consider: (1) the deliberateness and seriousness of the violation; (2) the degree of transferability of the violation to other products; and, (3) any history of prior violations. *Telebrands,* 457 F.2d at 358; *Kraft,* 970 F.2d at 326. Applying these factors to the facts of this case, in order to provide adequate consumer protection, the fencing-in relief in this Order is appropriate.

(1) Deliberateness and seriousness of the violation

In weighing the deliberateness of the violation, the evidence shows that Respondents made numerous deceptive representations over the Internet, in their publications, and through the DCO radio program, over the course of several years. Respondents were aware that they were making representations that could be deemed unlawful by governing authorities. *See* F. 215 (DCO HealthWatch radio program, where James Feijo stated that "the FTC, the FDA, the Canadian Government don't like the fact that we've told people about what to do about natural methods of health and healing, especially cancer"); F. 217 (DCO HealthWatch radio program, in which Patricia Feijo advised an individual whose father was diagnosed

with colon cancer that she should get her father "on . . . GDU, BioShark and 7 Herb Formula. And if you can get him to, you know, go right now to the website, [to download] How To Fight Cancer Is Your Choice, or you can get him a hard copy from our order center, while we have them. It's what the FTC wants to shut us down over and they certainly want us to, you know, crash the website and they want to, you know, burn our material.").

In weighing the seriousness of the violation, the evidence shows that the representations are health-related claims, *see supra* III D 1-2, and in some instances suggested that individuals forego traditional cancer treatments in favor of purchasing and consuming the Challenged Products. *E.g.*, F. 260 (During the July 8, 2008 DCO HealthWatch radio program, in response to a caller's concern about colon cancer and whether the caller should follow her doctor's recommendation of a colonoscopy, James Feijo stated, "Polyps are nothing . . . Polyps should be left alone."); F. 214 (2008 DCO HealthWatch radio program, in which James Feijo stated, "Here's a testimony from Pastor Wayne Hamm, Henderson, Nevada. He had the Gulf War illness. He was told that he needed surgery and radiation treatment for his cancer, that he developed skin cancer because of the Gulf War, he was exposed out there. He didn't take it. He decided to use Daniel Chapter One 7 Herb Formula, internally and topically. He also used Ezekiel Oil topically, BioShark and GDU. [His] skin cleared up after a few months in the late 1980s [sic], early '99,

[he] was told there was no trace of cancer."). There is a potential harm if a cancer patient foregoes potentially beneficial therapy and replaces it with one or more of the Challenged Products. F. 356. In addition, taking the Challenged Products could cause a dangerous interaction with drugs. F. 357. "When drug advertising is at issue, the potential health hazards may well justify a more sweeping order than would be proper were the Commission dealing with a less consequential area." *American Home Prods. v. FTC,* 695 F.2d at 706. Here, where Respondents intentionally represented that the Challenged Products could prevent, treat, or cure cancer, through numerous publications and websites, the deliberateness and seriousness of the violation weighs heavily in favor of the Order encompassing a broad range of products.

(2) Degree of transferability

A violation is transferrable where other products could be sold utilizing similar techniques. *FTC v. Colgate-Palmolive,* 380 U.S. at 394-95; *Sears v. FTC,* 676 F.2d at 392. For example, "misrepresenting that doctors prefer a product, or that tests prove the product's superiority, is a form of deception that could readily be employed for any non-prescription drug product." *American Home Prods. Corp. v. FTC,* 695 F.2d at 708. In this case, the claims that the Challenged Products prevent, treat, or cure cancer, and the use of testimonials by doctors and consumers to make such claims, could readily be employed for any dietary supplement. Thus, transferability is a significant

factor in favor of provisions in the Order encompassing a broad range of products.

(3) History of violations

No evidence was introduced or argument made to indicate that Respondents have a history of prior violations of the FTC Act. However, "the more egregious the facts with respect to a particular element, the less important it is that another negative factor be present. In the final analysis, [courts] look to the circumstances as a whole and not to the presence or absence of any single factor." *Sears v. FTC,* 676 F.2d at 392; *see also Kraft v. FTC,* 970 F.2d at 327. In *Telebrands,* the Court of Appeals upheld the Commission's conclusion that the strength of the evidence as to the first two factors sufficiently established that there was a reasonable relationship between the remedy and the violation, and it was not necessary to also consider any prior consent orders. *Telebrands,* 457 F.2d at 362. Thus, while here there is no history of violations which would weigh against the Order encompassing a broad range of products, that factor is less important, taking into account the circumstances as a whole. Accordingly, weighing all of the factors, the fencing-in relief in the attached Order bears a reasonable relationship to Respondents' violations of the FTC Act.

c. Requirement of a letter to consumers

The proposed order requires Respondents to mail a letter to each consumer of the Challenged Products, to inform him or her that the FTC has found that Respondents' advertising claims for these products were false and unsubstantiated and that the FTC has issued an Order prohibiting Respondents from making those claims in the future. It is appropriate to require Respondents to mail a letter to consumers to inform them of those findings. *E.g., FTC v. Natural Solution, Inc.*, No. CV 06-06112-JFW (C.D. Cal. Sept. 4, 2007). However, the proposed letter attached to the Complaint will be modified in two respects.

First, the proposed letter attached to the Complaint could be seen as requiring Respondents to adopt as their own statements and opinions that are contrary to the beliefs to which Respondents testified at trial. Therefore, the letter is modified to make it clear that the information contained in the letter is information that the FTC has required Respondents to transmit to consumers. Second, the letter is modified to reflect the fact that consumers purchased the Challenged Products not only through the DCO websites, but also through the toll-free number to DCO's call center.

d. Summary of remedy

The Order entered herewith is sufficiently clear and precise and is reasonably related to the unlawful acts or practices found to exist.

IV. SUMMARY OF CONCLUSIONS OF LAW

1. Complaint Counsel bears the burden of proving jurisdiction and liability by a preponderance of evidence.

2. Respondent Daniel Chapter One ("DCO") engages in business for its own profit or that of its sole member, Respondent James Feijo.

3. Respondent Daniel Chapter One ("DCO") is a corporation, as "corporation" within the meaning of "corporation" in Section 4 of the Federal Trade Commission Act.

4. Respondent James Feijo directed and controlled the acts and practices of DCO and may be held liable under the FTC Act for the violations of DCO.

5. Respondents' sales of BioShark, 7 Herb Formula, GDU, and BioMixx, the "Challenged Products," are in or affect commerce, as required by the FTC Act, 15 U.S.C. § 45(a)(1).

6. The Commission has jurisdiction over Respondents, and the conduct challenged in the Complaint, under Sections 4 and 5 of the FTC Act. 15 U.S.C. § 44, 45.

7. The materials disseminated by Respondents over the Internet constitute advertisements under Section 12 of the FTC Act. 15 U.S.C. § 52.

8. The materials disseminated by Respondents over the Internet were for the purpose of inducing and did induce purchases of the Challenged Products in or affecting commerce, under Section 12 of the FTC Act. 15 U.S.C. §§ 52, 55.

9. The Challenged Products constitute "food" or "drugs," under Section 12 of the FTC Act. 15 U.S.C. § 55.

10. The overall, net impression created by the Respondents' advertisements is that the Challenged Products, either alone or in combination with each other or other DCO products, prevent, treat, or cure cancer, inhibit tumors, or ameliorate the adverse effects of radiation or chemotherapy.

11. The disclaimer language, which appears on some of the advertisements, is not prominent or unambiguous, creates confusion with contradictory messages, and thus is not adequate for Respondents to avoid liability.

12. Extrinsic evidence is not required to interpret Respondents' advertisements or to interpret the claims from the perspective of a particular targeted group.

13. Extrinsic evidence is not required to interpret Respondents' advertisements because the meaning of the advertisements is reasonably clear from a facial review.

14. The claims made by Respondents are objective claims that relate to the attributes, performance, or efficacy of the Challenged Products.

15. Objective product claims carry with them the express or implied representation that Respondents had a reasonable basis substantiating the claims at the time the claims were made.

16. The claims made by Respondents are non-establishment claims and relate to health and safety.

17. Health-related efficacy claims, including claims made about dietary supplements must be substantiated by competent and reliable scientific evidence on the product itself. Testing only component ingredients is insufficient, unless the testing is on an exact duplicate of the product's combination of active ingredients.

18. Respondents did not possess or rely upon competent and reliable scientific evidence to substantiate their claims that the Challenged Products are effective, either alone or in combination with each other or other DCO products, in the prevention, treatment, or cure of cancer, tumors, or side effects of radiation or chemotherapy.

19. By showing that Respondents lacked a reasonable basis for their claims, Complaint Counsel has demonstrated that Respondents' statements are deceptive or misleading.

20. Respondents' claims relate to health concerns, involve information that is important to consumers and likely to affect their choice of or conduct

regarding the Challenged Products, and are therefore material.

21. Respondents' representations constitute commercial speech that is false, deceptive, or misleading, and are therefore not protected by the First Amendment.

22. The FTC's action and the Order entered herewith do not constitute an unconstitutional prior restraint.

23. All defenses raised by Respondents have been considered and rejected as lacking in merit, regardless of whether they are expressly addressed in this Initial Decision.

24. Respondents DCO and James Feijo are liable for violating Sections 5(a) and 12 of the FTC Act. 15 U.S.C. §§ 45(a), 52.

25. Individual Respondent James Feijo participated directly in and had the authority to control the deceptive representations at issue in this case. Accordingly, James Feijo is individually liable for practices of Respondent DCO found to be in violation of Sections 5 and 12 of the FTC Act.

26. The appropriate remedy is an order requiring Respondents to cease and desist from making the types of misrepresentations challenged in the Complaint.

27. Fencing-in relief is appropriate where, after examining circumstances of the case as a whole, it bears a reasonable relationship to a violation of the FTC Act.

28. The Order also provides fencing-in relief, requiring Respondents to possess competent and reliable scientific evidence supporting certain future claims about any dietary supplement, food, drug, or other health-related product, service, or program.

29. The Order attached herewith is clear and reasonably related to the proven violations.

ORDER

For purposes of this order the following definitions apply:

1. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

2. "Covered Product or Service" shall mean any dietary supplement, food, drug, or other health-related product, service, or program, including, but not limited to, BioShark, 7 Herb Formula, GDU, and BioMixx.

3. "Food" and "drug" shall mean "food" and "drug" as defined in Section 15 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 55.

4. "Advertisement" means any written or verbal statement, illustration, or depiction that is designed to effect

a sale or to create interest in the purchasing of goods or services, whether it appears in a book, brochure, newspaper, magazine, pamphlet, leaflet, circular, mailer, book insert, letter, catalogue, poster, chart, billboard, public transit card, point of purchase display, packaging, package insert, label, film, slide, radio, television or cable television, video news release, audio program transmitted over a telephone system, infomercial, the Internet, e-mail, or in any other medium.

5. Unless otherwise specified, "Respondents" shall mean Daniel Chapter One and its successors and assigns, affiliates, or subsidiaries, and its officer, James Feijo, individually and as an officer of the corporation; and each of the above's agents, representatives, and employees.

6. "Commerce" shall mean "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

7. "Endorsement" shall mean "endorsement" as defined in 16 C.F.R. § 255.0(b).

I.

IT IS HEREBY ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of BioShark, 7 Herb Formula, GDU, and BioMixx, or any substantially similar health-related

program, service, or product, or any other Covered Product or Service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of product or program names or endorsements, that such health-related program, service, product, or Covered Product or Service prevents, treats, or cures or assists in the prevention, treatment, or cure of any type of tumor or cancer, including but not limited to representations that:

1. BioShark inhibits tumor growth;
2. BioShark is effective in the treatment of cancer;
3. 7 Herb Formula is effective in the treatment or cure of cancer;
4. 7 Herb Formula inhibits tumor formation;
5. GDU eliminates tumors;
6. GDU is effective in the treatment of cancer;
7. BioMixx is effective in the treatment of cancer; or
8. BioMixx heals the destructive effects of radiation or chemotherapy;

unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that Respondents, directly or through any person, corporation, partnership, subsidiary, division, trade name, or other device,

in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product or Service, in or affecting commerce, shall not make any representation, in any manner, directly or by implication, including through the use of a product name, endorsement, depiction, or illustration, about the efficacy, performance, or health-related benefits of any Covered Product or Service unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that:

A. Nothing in this order shall prohibit Respondents from making any Representation for any drug that is permitted in labeling for such drug under any tentative or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. Nothing in this order shall prohibit Respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

IV.

IT IS FURTHER ORDERED that:

A. Respondents shall, within seven (7) days after the date of service of this order, deliver to the Commission a list, in the form of a sworn affidavit, of all consumers who purchased BioShark, 7 Herb Formula, GDU, and/or BioMixx, on or after January 1, 2005 through the date of service of this order. Such list shall include each consumer's name and address, the product(s) purchased, and, if available, the consumer's telephone number and email address;

B. Within forty-five (45) days after the date of service of this order, Respondents shall send by first class mail, postage prepaid, an exact copy of the notice attached as Attachment A to all persons identified in Part IV.A. above. The face of the envelope containing the notice shall be an exact copy of Attachment B. The mailing shall not include any other documents; and

C. Except as provided in this order, Respondents, and their officers, agents, servants, employees, attorneys, and representatives shall not sell, rent, lease, transfer, or otherwise disclose the name, address, telephone number, credit card number, bank account number, e-mail address, or other identifying information of any person who paid any money to any Respondent, at any time prior to the issuance of this order, in connection with the purchase of BioShark, 7 Herb Formula, GDU, and/or BioMixx. *Provided, however,* that Respondents may disclose such identifying information to the FTC pursuant to

Part IV.A., above, or any law enforcement agency, or as required by any law, regulation, or court order.

V.

IT IS FURTHER ORDERED that for a period of five (5) years after the last date of dissemination of any representation covered by this order, Respondents shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All advertisements and promotional materials containing the representation;

B. All materials that were relied upon in disseminating the representation; and

C. All tests, reports, studies, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VI.

IT IS FURTHER ORDERED that Respondents shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure

from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VII.

IT IS FURTHER ORDERED that Respondent Feijo, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include the individual Respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VIII.

IT IS FURTHER ORDERED that Respondent DCO and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the

emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. **Provided, however**, that, with respect to any proposed change in the corporation about which Respondent DCO learns less than thirty (30) days prior to the date such action is to take place, Respondent DCO shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

IX.

IT IS FURTHER ORDERED that Respondents shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

X.

IT IS FURTHER ORDERED that this order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade

Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; **provided, however,** that the filing of such a complaint will not affect the duration of:

A. Any paragraph in this order that terminates in less than twenty (20) years;

B. This order's application to any Respondent that is not named as a defendant in such complaint; and

C. This order if such complaint is filed after the order has terminated pursuant to this paragraph.

Provided further, that if such complaint is dismissed or a federal court rules that the Respondents did not violate any provision of this order, and the dismissal is either not appealed or upheld on appeal, then the order will terminate according to this paragraph as though the complaint was never filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

ORDERED: /s/ D M Chappell
D. Michael Chappell
Chief Administrative
Law Judge

Date: August 5, 2009

ATTACHMENT A

LETTER TO BE SENT BY FIRST CLASS MAIL
[To be printed on letterhead of Daniel Chapter One]

[Name and address of recipient] [Date]

Dear [Recipient]:

Our records show that you bought **[name of products]** from our website **[name of website]** or through our call center using our toll free number. We are writing to tell you that the Federal Trade Commission ("FTC") has found that our advertising claims for these products were false or unsubstantiated, and has issued an Order prohibiting us from making those claims in the future.

The Order entered against us by the FTC also requires that we send you the following information about the scientific evidence on these products:

> Very little scientific research has been done concerning shark cartilage, cat's claw, burdock root, Siberian ginseng, sheep sorrel, slippery elm, watercress, Turkey rhubarb root, bromelain, turmeric, quercetin, feverfew, boron, goldenseal, echinacea, and ginseng as a means of prevention, treatment, or cure for cancer in humans. The scientific studies that have been done do not demonstrate that any of these ingredients, which are included in BioShark, 7 Herb Formula, GDU, and BioMixx, are effective when used for prevention or treatment for cancer in humans.

It is very important that you talk to your doctor or health care provider before using any alternative or herbal product, including shark cartilage, cat's claw, burdock root, Siberian ginseng, sheep sorrel, slippery elm, watercress, Turkey rhubarb root, bromelain, turmeric, quercetin, feverfew, boron, goldenseal, echinacea, and ginseng. Speaking with your doctor is important to make sure that all aspects of your medical treatment work together. Things that seem safe, such as certain foods, herbs, or pills, may interfere or affect your cancer or other medical treatment, or other medicines you might be taking. Some herbs or other complementary or alternative treatments may keep your medicines from doing what they are supposed to do, or could be harmful when taken with other medicines or in high doses. It also is very important that you talk to your doctor or health care provider before you decide to take any alternative or herbal product, including shark cartilage, cat's claw, burdock root, Siberian ginseng, sheep sorrel, slippery elm, watercress, Turkey rhubarb root, bromelain, turmeric, quercetin, feverfew, boron, goldenseal, echinacea, and ginseng, instead of taking conventional cancer treatments that have been scientifically proven to be safe and effective in humans.

If you would like further information about complementary and alternative treatments for cancer, the following Internet web sites may be helpful:

1. The National Cancer Institute: www.cancer.gov/cancertopics/pdq; or

2. The National Center for Complementary and Alternative Medicines: www.nccam.nih.gov.

You may also contact the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER or 1-800-422-6237.

Sincerely,

ATTACHMENT B

Daniel Chapter One
1028 East Main Road
Portsmouth, Rhode Island, 02871

[name and address of purchaser]

GOVERNMENT ORDERED NOTICE

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 10-1064 **September Term 2010**
FTC-9329

Filed On: February 16, 2011

Daniel Chapter One, a corporate sole and James Feijo, individually, and as officer of Daniel Chapter One,

Petitioners

v.

Federal Trade Commission,

Respondent

BEFORE: Sentelle, Chief Judge, and Ginsburg, Henderson, Rogers, Tatel Garland, Brown, Griffith, and Kavanaugh, Circuit Judges

ORDER

Upon consideration of petitioners' petition for rehearing en banc, and the absence of a request by any member of the court for a vote, it is

ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Jennifer M. Clark
Deputy Clerk

Federal Trade Commission Act

15 U.S.C. § 44. Definitions

(Sec. 4 of the FTCA)

The words defined in this section shall have the following meaning when found in this subchapter, to wit:

* * *

"Corporation" shall be deemed to include any company, trust, so-called Massachusetts trust, or association, incorporated or unincorporated, which is organized to carry on business for its own profit or that of its members, and has shares of capital or capital stock or certificates of interest, and any company, trust, so-called Massachusetts trust, or association, incorporated or unincorporated, without shares of capital or capital stock or certificates of interest, except partnerships, which is organized to carry on business for its own profit or that of its members.

* * *

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15 U.S.C. § 45. Unfair methods of competition unlawful; prevention by Commission

(Sec. 5 of the FTCA)

(a) Declaration of unlawfulness; power to prohibit unfair practices; inapplicability to foreign trade

(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.

(2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations, except banks, savings and loan institutions described in section 57a(f)(3) of this title, Federal credit unions described in section 57a(f)(4) of this title, common carriers subject to the Acts to regulate commerce, air carriers and foreign air carriers subject to part A of subtitle VII of Title 49, and persons, partnerships, or corporations insofar as they are subject to the Packers and Stockyards Act, 1921, as amended [7 U.S.C.A. § 181 et seq.], except as provided in section 406(b) of said Act [7 U.S.C.A. § 227(b)], from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

(3) This subsection shall not apply to unfair methods of competition involving commerce with foreign nations (other than import commerce) unless –

(A) such methods of competition have a direct, substantial, and reasonably foreseeable effect –

(i) on commerce which is not commerce with foreign nations, or on import commerce with foreign nations; or

(ii) on export commerce with foreign nations, of a person engaged in such commerce in the United States; and

(B) such effect gives rise to a claim under the provisions of this subsection, other than this paragraph.

If this subsection applies to such methods of competition only because of the operation of subparagraph (A)(ii), this subsection shall apply to such conduct only for injury to export business in the United States.

(4)(A) For purposes of subsection (a) of this section, the term "unfair or deceptive acts or practices" includes such acts or practices involving foreign commerce that –

(i) cause or are likely to cause reasonably foreseeable injury within the United States; or

(ii) involve material conduct occurring within the United States.

(B) All remedies available to the Commission with respect to unfair and deceptive acts or practices shall be available for acts and practices described in this paragraph, including restitution to domestic or foreign victims.

(b) Proceeding by Commission; modifying and setting aside orders

Whenever the Commission shall have reason to believe that any such person, partnership, or corporation has been or is using any unfair method of competition or unfair or deceptive act or practice in or affecting commerce, and if it shall appear to the Commission that a proceeding by it in respect thereof would be to the interest of the public, it shall issue and serve upon such person, partnership, or corporation a complaint stating its charges in that respect

and containing a notice of a hearing upon a day and at a place therein fixed at least thirty days after the service of said complaint. The person, partnership, or corporation so complained of shall have the right to appear at the place and time so fixed and show cause why an order should not be entered by the Commission requiring such person, partnership, or corporation to cease and desist from the violation of the law so charged in said complaint. Any person, partnership, or corporation may make application, and upon good cause shown may be allowed by the Commission to intervene and appear in said proceeding by counsel or in person. The testimony in any such proceeding shall be reduced to writing and filed in the office of the Commission. If upon such hearing the Commission shall be of the opinion that the method of competition or the act or practice in question is prohibited by this subchapter, it shall make a report in writing in which it shall state its findings as to the facts and shall issue and cause to be served on such person, partnership, or corporation an order requiring such person, partnership, or corporation to cease and desist from using such method of competition or such act or practice. Until the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, or, if a petition for review has been filed within such time then until the record in the proceeding has been filed in a court of appeals of the United States, as hereinafter provided, the Commission may at any time, upon such notice and in such manner as it shall deem proper, modify or set aside, in whole or in part, any report or any order made or issued by it under this

section. After the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, the Commission may at any time, after notice and opportunity for hearing, reopen and alter, modify, or set aside, in whole or in part, any report or order made or issued by it under this section, whenever in the opinion of the Commission conditions of fact or of law have so changed as to require such action or if the public interest shall so require, except that (1) the said person, partnership, or corporation may, within sixty days after service upon him or it of said report or order entered after such a reopening, obtain a review thereof in the appropriate court of appeals of the United States, in the manner provided in subsection (c) of this section; and (2) in the case of an order, the Commission shall reopen any such order to consider whether such order (including any affirmative relief provision contained in such order) should be altered, modified, or set aside, in whole or in part, if the person, partnership, or corporation involved files a request with the Commission which makes a satisfactory showing that changed conditions of law or fact require such order to be altered, modified, or set aside, in whole or in part. The Commission shall determine whether to alter, modify, or set aside any order of the Commission in response to a request made by a person, partnership, or corporation under paragraph[1] (2) not later than 120 days after the date of the filing of such request.

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[1] So in original. Probably should be "clause".

(c) Review of order; rehearing

Any person, partnership, or corporation required by an order of the Commission to cease and desist from using any method of competition or act or practice may obtain a review of such order in the court of appeals of the United States, within any circuit where the method of competition or the act or practice in question was used or where such person, partnership, or corporation resides or carries on business, by filing in the court, within sixty days from the date of the service of such order, a written petition praying that the order of the Commission be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Commission, and thereupon the Commission shall file in the court the record in the proceeding, as provided in section 2112 of Title 28. Upon such filing of the petition the court shall have jurisdiction of the proceeding and of the question determined therein concurrently with the Commission until the filing of the record and shall have power to make and enter a decree affirming, modifying, or setting aside the order of the Commission, and enforcing the same to the extent that such order is affirmed and to issue such writs as are ancillary to its jurisdiction or are necessary in its judgement to prevent injury to the public or to competitors pendente lite. The findings of the Commission as to the facts, if supported by evidence, shall be conclusive. To the extent that the order of the Commission is affirmed, the court shall thereupon issue its own order commanding obedience to the terms of such order of the Commission. If either party shall apply to

the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Commission, the court may order such additional evidence to be taken before the Commission and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Commission may modify its findings as to the facts, or make new findings, by reason of the additional evidence so taken, and it shall file such modified or new findings, which, if supported by evidence, shall be conclusive, and its recommendation, if any, for the modification or setting aside of its original order, with the return of such additional evidence. The judgment and decree of the court shall be final, except that the same shall be subject to review by the Supreme Court upon certiorari, as provided in section 1254 of Title 28.

(d) Jurisdiction of court

Upon the filing of the record with it the jurisdiction of the court of appeals of the United States to affirm, enforce, modify, or set aside orders of the Commission shall be exclusive.

(e) Exemption from liability

No order of the Commission or judgement of court to enforce the same shall in anywise relieve or absolve any person, partnership, or corporation from any liability under the Antitrust Acts.

(f) Service of complaints, orders and other processes; return

Complaints, orders, and other processes of the Commission under this section may be served by anyone duly authorized by the Commission, either (a) by delivering a copy thereof to the person to be served, or to a member of the partnership to be served, or the president, secretary, or other executive officer or a director of the corporation to be served; or (b) by leaving a copy thereof at the residence or the principal office or place of business of such person, partnership, or corporation; or (c) by mailing a copy thereof by registered mail or by certified mail addressed to such person, partnership, or corporation at his or its residence or principal office or place of business. The verified return by the person so serving said complaint, order, or other process setting forth the manner of said service shall be proof of the same, and the return post office receipt for said complaint, order, or other process mailed by registered mail or by certified mail as aforesaid shall be proof of the service of the same.

(g) Finality of order

An order of the Commission to cease and desist shall become final –

(1) Upon the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time; but the Commission may thereafter modify or set aside its order to the extent provided in the last sentence of subsection (b).

(2) Except as to any order provision subject to paragraph (4), upon the sixtieth day after such order is served, if a petition for review has been duly filed; except that any such order may be stayed, in whole or in part and subject to such conditions as may be appropriate, by –

(A) the Commission;

(B) an appropriate court of appeals of the United States, if (i) a petition for review of such order is pending in such court, and (ii) an application for such a stay was previously submitted to the Commission and the Commission, within the 30-day period beginning on the date the application was received by the Commission, either denied the application or did not grant or deny the application; or

(C) the Supreme Court, if an applicable petition for certiorari is pending.

(3) For purposes of subsection (m)(1)(B) of this section and of section 57b(a)(2) of this title, if a petition for review of the order of the Commission has been filed –

(A) upon the expiration of the time allowed for filing a petition for certiorari, if the order of the Commission has been affirmed or the petition for review has been dismissed by the court of appeals and no petition for certiorari has been duly filed;

(B) upon the denial of a petition for certiorari, if the order of the Commission has been affirmed or the

petition for review has been dismissed by the court of appeals; or

(C) upon the expiration of 30 days from the date of issuance of a mandate of the Supreme Court directing that the order of the Commission be affirmed or the petition for review be dismissed.

(4) In the case of an order provision requiring a person, partnership, or corporation to divest itself of stock, other share capital, or assets, if a petition for review of such order of the Commission has been filed –

(A) upon the expiration of the time allowed for filing a petition for certiorari, if the order of the Commission has been affirmed or the petition for review has been dismissed by the court of appeals and no petition for certiorari has been duly filed;

(B) upon the denial of a petition for certiorari, if the order of the Commission has been affirmed or the petition for review has been dismissed by the court of appeals; or

(C) upon the expiration of 30 days from the date of issuance of a mandate of the Supreme Court directing that the order of the Commission be affirmed or the petition for review be dismissed.

(h) Modification or setting aside of order by Supreme Court

If the Supreme Court directs that the order of the Commission be modified or set aside, the order of the

Commission rendered in accordance with the mandate of the Supreme Court shall become final upon the expiration of thirty days from the time it was rendered, unless within such thirty days either party has instituted proceedings to have such order corrected to accord with the mandate, in which event the order of the Commission shall become final when so corrected.

(i) Modification or setting aside of order by Court of Appeals

If the order of the Commission is modified or set aside by the court of appeals, and if (1) the time allowed for filing a petition for certiorari has expired and no such petition has been duly filed, or (2) the petition for certiorari has been denied, or (3) the decision of the court has been affirmed by the Supreme Court, then the order of the Commission rendered in accordance with the mandate of the court of appeals shall become final on the expiration of thirty days from the time such order of the Commission was rendered, unless within such thirty days either party has instituted proceedings to have such order corrected so that it will accord with the mandate, in which event the order of the Commission shall become final when so corrected.

(j) Rehearing upon order or remand

If the Supreme Court orders a rehearing; or if the case is remanded by the court of appeals to the Commission for a rehearing, and if (1) the time allowed for filing a petition for certiorari has expired, and no

such petition has been duly filed, or (2) the petition for certiorari has been denied, or (3) the decision of the court has been affirmed by the Supreme Court, then the order of the Commission rendered upon such, rehearing shall become final in the same manner as though no prior order of the Commission had been rendered.

(k) "Mandate" defined

As used in this section the term "mandate", in case a mandate has been recalled prior to the expiration of thirty days from the date of issuance thereof, means the final mandate.

(l) Penalty for violation of order; injunctions and other appropriate equitable relief Any person, partnership, or corporation who violates an order of the Commission after it has become final, and while such order is in effect, shall forfeit and pay to the United States a civil penalty of not more than $10,000 for each violation, which shall accrue to the United States and may be recovered in a civil action brought by the Attorney General of the United States. Each separate violation of such an order shall be a separate offense, except that in a case of a violation through continuing failure to obey or neglect to obey a final order of the Commission, each day of continuance of such failure or neglect shall be deemed a separate offense. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they

deem appropriate in the enforcement of such final orders of the Commission.

(m) Civil actions for recovery of penalties for knowing violations of rules and cease and desist orders respecting unfair or deceptive acts or practices; jurisdiction; maximum amount of penalties; continuing violations; de novo determinations; compromise or settlement procedure

(1)(A) The Commission may commence a civil action to recover a civil penalty in a district court of the United States against any person, partnership, or corporation which violates any rule under this chapter respecting unfair or deceptive acts or practices (other than an interpretive rule or a rule violation of which the Commission has provided is not an unfair or deceptive act or practice in violation of subsection (a)(1) of this section) with actual knowledge or knowledge fairly implied on the basis of objective circumstances that such act is unfair or deceptive and is prohibited by such rule. In such action, such person, partnership, or corporation shall be liable for a civil penalty of not more than $10,000 for each violation.

(B) If the Commission determines in a proceeding under subsection (b) of this section that any act or practice is unfair or deceptive, and issues a final cease and desist order, other than a consent order, with respect to such act or practice, then the Commission may commence a civil action to obtain a civil penalty in a district court of the United States

against any person, partnership, or corporation which engages in such act or practice –

(1) after such cease and desist order becomes final (whether or not such person, partnership, or corporation was subject to such cease and desist order), and

(2) with actual knowledge that such act or practice is unfair or deceptive and is unlawful under subsection (a)(1) of this section.

In such action, such person, partnership, or corporation shall be liable for a civil penalty of not more than $10,000 for each violation.

(C) In the case of a violation through continuing failure to comply with a rule or with subsection (a)(1) of this section, each day of continuance of such failure shall be treated as a separate violation, for purposes of subparagraphs (A) and (B). In determining the amount of such a civil penalty, the court shall take into account the degree of culpability, any history of prior such conduct, ability to pay, effect on ability to continue to do business, and such other matters as justice may require.

(2) If the cease and desist order establishing that the act or practice is unfair or deceptive was not issued against the defendant in a civil penalty action under paragraph (1)(B) the issues of fact in such action against such defendant shall be tried de novo. Upon request of any party to such an action against such defendant, the court shall also review the determination of law made by the Commission in the

proceeding under subsection (b) of this section that the act or practice which was the subject of such proceeding constituted an unfair or deceptive act or practice in violation of subsection (a) of this section.

(3) The Commission may compromise or settle any action for a civil penalty if such compromise or settlement is accompanied by a public statement of its reasons and is approved by the court.

(n) Standard of proof; public policy consideration

The Commission shall have no authority under this section or section 57a of this title to declare unlawful an act or practice on the grounds that such act or practice is unfair unless the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition. In determining whether an act or practice is unfair, the Commission may consider established public policies as evidence to be considered with all other evidence. Such public policy considerations may not serve as a primary basis for such determination.

15 U.S.C. § 52. Dissemination of false advertisements

(Sec. 12 of the FTCA)

(a) Unlawfulness

It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement –

(1) By United States mails, or in or having an effect upon commerce, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food, drugs, devices, services, or cosmetics; or

(2) By any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce, of food, drugs, devices, services, or cosmetics.

(b) Unfair or deceptive act or practice

The dissemination or the causing to be disseminated of any false advertisement within the provisions of subsection (a) of this section shall be an unfair or deceptive act or practice in or affecting commerce within the meaning of section 45 of this title.

TITLE 42 – THE PUBLIC HEALTH AND WELFARE CHAPTER 21B – RELIGIOUS FREEDOM RESTORATION

42 U.S.C. Sec. 2000bb. Congressional findings and declaration of purposes

(a) Findings

The Congress finds that –

(1) the framers of the Constitution, recognizing free exercise of religion as an unalienable right, secured its protection in the First Amendment to the Constitution;

(2) laws "neutral" toward religion may burden religious exercise as surely as laws intended to interfere with religious exercise;

(3) governments should not substantially burden religious exercise without compelling justification;

(4) in Employment Division v. Smith, 494 U.S. 872 (1990) the Supreme Court virtually eliminated the requirement that the government justify burdens on religious exercise imposed by laws neutral toward religion; and

(5) the compelling interest test as set forth in prior Federal court rulings is a workable test for striking sensible balances between religious liberty and competing prior governmental interests.

(b) Purposes

The purposes of this chapter are –

(1) to restore the compelling interest test as set forth in Sherbert v. Verner, 374 U.S. 398 (1963) and Wisconsin v. Yoder, 406 U.S. 205 (1972) and to guarantee its application in all cases where free exercise of religion is substantially burdened; and

(2) to provide a claim or defense to persons whose religious exercise is substantially burdened by government.

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42 U.S.C. Sec. 2000bb-1. Free exercise of religion protected

(a) In general

Government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability, except as provided in subsection (b) of this section.

(b) Exception

Government may substantially burden a person's exercise of religion only if it demonstrates that application of the burden to the person –

(1) is in furtherance of a compelling governmental interest; and

(2) is the least restrictive means of furthering that compelling governmental interest.

(c) Judicial relief

A person whose religious exercise has been burdened in violation of this section may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government. Standing to assert a claim or defense under this section shall be governed by the general rules of standing under article III of the Constitution.

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42 U.S.C. Sec. 2000bb-2. Definitions

As used in this chapter –

(1) the term "government" includes a branch, department, agency, instrumentality, and official (or other person acting under color of law) of the United States, or of a covered entity;

(2) the term "covered entity" means the District of Columbia, the Commonwealth of Puerto Rico, and each territory and possession of the United States;

(3) the term "demonstrates" means meets the burdens of going forward with the evidence and of persuasion; and

(4) the term "exercise of religion" means religious exercise, as defined in section 2000cc-5 of this title.

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42 U.S.C. Sec. 2000bb-3. Applicability

(a) In general

This chapter applies to all Federal law, and the implementation of that law, whether statutory or otherwise, and whether adopted before or after November 16, 1993.

(b) Rule of construction

Federal statutory law adopted after November 16, 1993, is subject to this chapter unless such law explicitly excludes such application by reference to this chapter.

(c) Religious belief unaffected

Nothing in this chapter shall be construed to authorize any government to burden any religious belief.

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42 U.S.C. Sec. 2000bb-4. Establishment clause unaffected

Nothing in this chapter shall be construed to affect, interpret, or in any way address that portion of the First Amendment prohibiting laws respecting the establishment of religion (referred to in this section as the "Establishment Clause"). Granting government funding, benefits, or exemptions, to the extent permissible under the Establishment Clause, shall not constitute a violation of this chapter. As used in this section, the term "granting", used with respect to government funding, benefits, or exemptions, does

not include the denial of government funding, benefits, or exemptions.

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42 Sec. 2000cc-5. Definitions

In this chapter:

* * *

(7) Religious exercise

(A) In general

The term "religious exercise" includes any exercise of religion, whether or not compelled by, or central to, a system of religious belief.

(B) Rule

The use, building, or conversion of real property for the purpose of religious exercise shall be considered to be religious exercise of the person or entity that uses or intends to use the property for that purpose.

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(3)

Supreme Court, U.S.
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No. 10-1292

IN THE

Supreme Court of the United States

DANIEL CHAPTER ONE, ET AL.,
Petitioners,
v.
FEDERAL TRADE COMMISSION,
Respondent.

On Petition for Writ of Certiorari
to the United States Court of Appeals
for the District of Columbia Circuit

BRIEF *AMICUS CURIAE* OF FOUNDATION FOR HEALTH CHOICE AND CITIZENS FOR HEALTH IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*[1]

The *Amici* herein are the Foundation for Health Choice, an organization of health care practitioners and consumers, and Citizens for Health, a natural health consumers' organization. Between them, these organizations have decades of involvement representing consumer rights in the health policy arena and represent tens of thousands of their members as well as the general public. Their interest is in protecting the rights of consumers to health choice and access to health information. They enter this case as *amici* in order to advance these important rights which they believe and assert are endangered unconstitutionally by the decision of the Federal Trade Commission (FTC) in this case. Without protection for these rights, not only will current consumers be denied self-determination in one of the most personal and private areas of life, but the development of new approaches to health care for the future will be stunted by the sacrifice of diversity to orthodoxy.

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[1] The parties were given timely notice of and have consented to the filing of this brief in letters of consent on file with the Clerk. No counsel for any party had any role in authoring this brief, and no one other than the *Amici Curiae* provided any monetary contribution to its preparation or submission. Counsel for *Amici* represented Petitioners in the administrative hearing phase of these proceedings but other counsel have represented Petitioners in all judicial phases of these proceedings over the past seventeen months.

SUMMARY OF ARGUMENT

The court should grant certiorari for the following reasons:

The issues presented in this case relate to a core legal principle that impacts large numbers of consumers, beyond the followers of Petitioner. The health maintenance concerns at the heart of this case are exactly the kind of concern that this court had in mind when it said, "...the particular consumer's interest in the free flow of commercial information, ...may be as keen, if not keener by far, than his interest in the day's most urgent political debate." *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976). The FTC's position, that only double blind, placebo controlled studies can constitute the "competent and reliable scientific evidence" required by the FTC statutory standard, is legislatively incorrect and Constitutionally impermissible. Petitioners provided expert testimony that their statements were supported by "competent and reliable scientific evidence." The FTC's response, adopted by the FTC Administrative Law Judge and by the Federal Trade Commission itself, was to enshrine the testimony of their single expert, that double blind, placebo controlled studies were the only applicable standard, as the law in this case. This decision deprives millions of consumers who are making decisions every day relying on the type of evidence presented by Petitioners' experts, of the right to make those decisions. The Constitution does

not permit the government to suppress consumer access to such information. Consumers have a Constitutionally protected basic human right, beyond the religious right of Petitioner's followers, to the information that Petitioners' experts, who the FTC accepted as experts, testified was supported by "competent and reliable scientific evidence" other than double blind, placebo controlled studies. In addition, Federal courts are increasingly being called upon to decide questions about FTC regulation of health claims for herbal and nutritional products such as those at issue in this case and guidance for them will help reduce social tension around food regulation.

This court should grant certiorari so that these issues, which are currently at the core of a national public debate about when and how less intrusive herbal and dietary remedies can be integrated into the conventional drug, radiation and surgery-based health care approaches, can be fully and finally made clear to consumers, producers, and regulators of health claims for foods and to the courts being asked to decide such controversies.

ARGUMENT

I. THIS COURT HAS HELD THAT COMMERCIAL SPEECH IS CONSTITUTIONALLY PROTECTED AND HEALTH CLAIMS FOR PRODUCTS CONSTITUTE COMMERCIAL

SPEECH AND ARE MATTERS OF OPINION RATHER THAN MATTERS OF FACT.

A. A Statement That A Substance Cures A Condition Is A Matter Of Opinion, Rather Than A Matter Of Fact.

In *United States v. Johnson*, 221 U.S. 488 (1911), Justices Oliver Wendell Holmes, for the majority, and Charles Evans Hughes, in dissent, set out a clear way to think about, and resolve, the issues presented in the present case. By reviewing their reasoning, this court can resolve a raging national controversy[2] over the role of claims about

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[2] Appeals courts are approaching this issue in varying ways, for example:

The U.S. Court of Appeals for the Tenth Circuit, in *Nutraceutical Corporation; Solaray, Inc., Plaintiffs-Appellees, v. Andrew Von Eschenbach, Acting Commissioner, U.S. Food and Drug Administration*, 459 F.3d 1033, August 17, 2006, reversed the lower court denial of the regulator's authority defining for the first time the standard of review that Congress intended for courts to use in reviewing actions of the federal agencies, finding that when Congress used the word *de novo* in the Dietary Supplement and Health Education Act of 1994 it did not intend to apply it to court review of agency actions.

Compare to:

The U.S. Court of Appeals for the Third Circuit, in *Federal Trade Commission, Appellant, v. Lane Labs-USA, Inc; Cartilage Consultants, Inc.; I. William Lane; Andrew J. Lane*, App No. 09-3909, 2010 WL 4226509 (3d Cir. Oct. 26, 2010),

reversed a lower court denial of regulatory authority but remanded the case for factual determination as to whether Lane Labs' alleged violations of a previous consent order were technical or inadvertent, allowing a substantial compliance defense if they were inadvertent.

The implication of the issue playing out in various courts is set forth in "Has the FTC Changed the Game On Advertising Substantiation?" by Randal Shaheen and Amy Ralph Mudge, *Antitrust*, Vol. 25, No. 1, Fall 2010 © 2010 by the American Bar Association. They say, citing David C. Vladeck, Director, Bureau of Consumer Protection, Fed. Trade Comm'n, Remarks Before the Council for Responsible Nutrition's Annual Symposium for the Dietary Supplement Industry, Priorities for Dietary Supplement Advertising Enforcement (Oct. 22, 2009), *http://www.ftc.gov/speeches/vladeck/091022vladeckcrnspeech.pdf*,

> Since its loss in *Lane Labs*, FTC staff has stated that it intended to modify its traditional requirement of competent and reliable scientific evidence."23The Director of the Bureau of Consumer Protection, David Vladeck (a seasoned public interest litigation lawyer), has also stated that he would seek more precise order language as to the amount and type of scientific evidence necessary to support health claims, as well as pursue efforts to harmonize FTC with FDA requirements. He indicated that an "outlier study," even if well conducted, should not be sufficient basis for a health claim.

To protect against one "outlier" study in the enforcement of a consent order the FTC has enthroned the double blind placebo controlled study as the sole support for its enforcement actions.

complementary and alternative approaches to health, such as the use of herbs and nutrients, as defined by the National Institutes of Health's National Center for Complementary and Alternative Medicine (NCCAM), and provide a Constitutional context to guide future action by producers, sellers, regulators, consumers and courts.

The *Johnson* case addressed the fact that Mr. Johnson shipped a drug from Missouri to Washington, DC, claiming on the label that it would cure cancer when he knew it would not cure cancer. *Johnson*, p. 488. The lower court held that the Pure Food and Drug Act of 1906 did not make such statements illegal. This court affirmed the lower court decision, with Justice Hughes, joined by Justice Harlan and Justice Day, dissenting.

Justice Holmes, writing for the court majority, said, "It is a postulate, as the case comes before us, that in a certain sense the statement on the label was false, or, at least, misleading. What we have to decide is whether such misleading statements are aimed at and hit by the words of the act. It seems to us that the words used convey to an ear trained to the usages of English speech a different aim; and although the meaning of a sentence is to be felt rather than to be proved, generally, here, the impression may be strengthened by argument, as we shall try to show." *Johnson*, p. 488.

Justice Holmes's argument concluded that Congress intended the Pure Food and Drug Act of 1906 to restrict false or misleading claims about the

content, ingredients, origin, etc., of a product, "matters of fact" he called them, and did not intend to restrict claims about what a product might do, which he considered "matters of opinion." Congress, he said, "was much more likely to regulate commerce in food and drugs with reference to plain matters of fact, so that food and drugs should be what they professed to be, when the kind was stated, than to distort the uses of its constitutional power to establishing criteria in regions where opinions are far apart. See *American School v. McAnnulty*, 187 U. S. 94, 47 L. ed. 90, 23 Sup. Ct. Rep. 33." *Johnson*, p. 488.

Justice Hughes, writing the dissent, said, "The question, then, is whether, if an article is shipped in interstate commerce, bearing on its label a representation that it is a cure for a given disease, when, on a showing of the facts, there would be a unanimous agreement that it was absolutely worthless and an out-and-out cheat, the act of Congress can be said to apply to it. To my mind the answer appears clear." *Johnson*, p. 489. To Justice Hughes the clear answer was "yes," the statutes applied. In a case where the authorities proved by a "showing of the facts, there would be a unanimous agreement that it was absolutely worthless and an out-and-out cheat" the statue applied.

The *Johnson* case addresses the question of how the law, as applied by regulators, should deal with differences of opinion that cannot easily be settled by facts. While they disagreed over the application of the 1906 Act in the Johnson case, Holmes and

Hughes agreed that in order to act the authorities need to rely on fact, not opinion. Thus Justice Hughes argued that, in a case where it was established as a matter of fact that a claim for a product was "absolutely worthless and an out-and-out cheat," Congress could act against it. The matter that these two giants of the law struggled over in *Johnson* was addressed in a 1974 FTC proceeding that proposed banning the word "organic," from all commerce. The FTC ALJ rejected the FTC proposal saying "to ban the word 'organic',,,[is] a legal, if not a linguistic error..."[3]

The *Johnson* case did not reach the constitutional question, because the majority disposed of it as a legislative interpretation case because Congress's intent could be interpreted as dealing purely with facts. Petitioners in this case now clearly put before the court the question of how far regulators can go in banning commercial words and statements that current medical/health orthodoxy, represented by double blind, placebo controlled studies, finds offensive to its views. In this case Petitioners

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[3] Proposed Trade Regulation Rule: Food Advertising [16 CFR Part 437] Report of the Presiding Officer Public Record Number 215-40, p. 239, February 21, 1978. If the FTC had been successful in banning the word "organic" from commerce it is unlikely that the current multibillion dollar organic food business, supported by millions of American consumers, would have come into existence.

presented expert witnesses who testified that the statements made by Petitioners were supported by "competent and reliable scientific evidence." The FTC rejected this testimony and banned the statements. The court needs to review this debate to clarify the terms on which the Constitution allows it to be conducted.

II. THE FIRST AMENDMENT PROTECTS THE EXPRESSION OF OPINION

A. Robust Commercial Speech Is An Important National Asset

In *FTC v. QT*, 512 F.3d 858 (7th Cir., 2008) the U. S. Court of Appeals for the Seventh Circuit spelled out the argument being placed before this court by Petitioners.

> Defendants maintain that the magistrate judge subjected their statements to an excessively rigorous standard of proof. Some passages in the opinion could be read to imply that any statement about a product's therapeutic effects must be deemed false unless the claim has been verified in a placebo-controlled, double-blind study: that is, a study in which some persons are given the product whose effects are being investigated while others are given a placebo (with the allocation made at random), and neither the person who

> distributes the product nor the person who measures the effects knows which received the real product. Such studies are expensive, not only because of the need for placebos and keeping the experimenters in the dark, but also because they require large numbers of participants to achieve statistically significant results. Defendants observe that requiring vendors to bear such heavy costs may keep useful products off the market (this has been a problem for drugs that are subject to the FDA's testing protocols) and prevent vendors from making truthful statements that will help consumers locate products that will do them good.
>
> Nothing in the Federal Trade Commission Act, the foundation of this litigation, requires placebo-controlled, double-blind studies. The Act forbids false and misleading statements, and a statement that is plausible but has not been tested in the most reliable way cannot be condemned out of hand. The burden is on the Commission to prove that the statements are false.

Petitioners ask and *Amici* here support their request that this court resolve the question of the degree to which the First Amendment protects commercial speech that makes health claims based on evidence other than double blind, placebo

controlled clinical trials. The FTC is insistent on asserting that a double blind, placebo controlled study is the only kind of study that can provide "competent and reliable scientific evidence" that a commercial speech statement is not false or misleading. Petitioners ask this court to resolve this issue, and contend that the FTC ruling violates this court's interpretation of the protections provided to commercial speech by the Constitution. Petitioners urge the court to make the position of the Seventh Circuit in *FTC v. QT* its holding in this case.

In another case, *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), strikingly similar to this case and involving comparable marketing claims for dietary supplements, the U.S. Court of Appeals for the District of Columbia rejected the position taken by the FTC in this case. The *Pearson* court applied the First Amendment commercial speech doctrine to claims that did not meet an FDA "scientific" standard—"significant scientific agreement"—similar to the standard relied on by the FTC in this case.

In *Pearson*, as here, marketers of dietary supplements made health claims not supported by double blind, placebo controlled studies. *Compare Pearson*, 164 F.3d at 652 *with* FTC Initial Decision, pp. 83-95. In *Pearson*, as here, the government agencies found these claims misleading because they did not meet the agencies' "scientific" standards. *Compare Pearson*, 164 F.3d at 652-55 *with* FTC Initial Decision, pp. 99-106. Thus, in *Pearson*, as here, the government agencies asserted that the

health claims were "entirely outside the protection of the First Amendment." *Compare Pearson*, 164 F.3d at 655 *with* FTC Initial Decision, pp. 115-16. In *Pearson*, however, the Court of Appeals rejected the agency's claim (calling it "almost frivolous"), whereas in this case, the FTC and the lower court embraced it.

The *Pearson* decision relied on three prior cases applying First Amendment commercial speech doctrine — *In re R.M.J.*, 455 U.S. 191 (1982), *Ibanez*, 512 U.S. 136 (1990), and *Peel v. Attorney Registration and Disciplinary Comm'n. of Illinois*, 496 U.S. 91 (1990). The court in *Pearson* rejected the FDA's contention that health claims, unless consistent with the then-prevailing scientific consensus, were inherently misleading and thus not protected free speech. It found the FDA's argument unpersuasive because it was based upon the unconstitutional "paternalistic assumption" that the ordinary consumer was unable to make an informed and independent judgment on the truthfulness of health claims for vitamins and other dietary supplements. *Pearson*, 164 F.3d at 655.

In this case the FTC dismissed *RMJ*, *Ibanez*, and *Peel*, as "inapposite." FTC Initial Decision, p. 116. In fact, the FTC embraced the "paternalistic assumption" that health claims must meet a "high level of substantiation, such as scientific tests" because it is "difficult or impossible for consumers to evaluate [health claims] for themselves." FTC Initial Decision, p. 102. In so ruling, the FTC violated the "general rule ... that the speaker and the audience,

not the government, assess the value of the information presented." *Edenfield v. Fane*, 507 U.S. 761, 767 (1993) [emphasis added]. Indeed, the FTC's paternalistic insistence that Petitioners' claims be measured by current scientific orthodoxy directly contravenes the First Amendment's commitment to "the free flow of commercial information" which, to an individual consumer seeking a solution to a personal health need, "may be as keen, if not keener by far, than his interest in the day's most urgent political debate." *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 763 (1976).

The *Pearson* court recognized what the FTC did not — the First Amendment protects the people from government suppression of commercial information if that suppression rests upon a paternalistic policy. Indeed, from the beginning of the development of its First Amendment commercial speech doctrine, the court has consistently rejected paternalistic justifications for suppression of information, knowing "that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to **open** the channels of communication rather than to close them." *Thompson v. Western States Medical Center*, 535 U.S. 357, 375 (2002), quoting from *Virginia State Board of Pharmacy*, 425 U.S. at 769 [emphasis added].

This does not mean that the government may not protect the people from demonstrably fraudulent

advertising. The complaint in this case, however, does not allege that Petitioners' health claims are false; rather, it rests upon the allegation that Petitioners did not have a "reasonable basis" of the sort that the FTC would accept for its health claims: double blind, placebo controlled, clinical trials. FTC Initial Decision, pp. 67, 99. These two standards — falsity in fact and lack of a reasonable basis — are drastically different. The "falsity" theory **requires the government** to "carry the burden of proving that the express or implied message conveyed by the ad is false." FTC Initial Decision, p. 99, n.4. The "reasonable basis theory" **requires the marketer** to demonstrate that it relied upon "competent and reliable scientific evidence," in this instance defined as double-blind, placebo-controlled clinical trials, for its health claims. FTC Initial Decision, p. 100.

The Petitioners argue, and *Amici* support, first, that it is the government's responsibility to show that the Petitioners in this case did not have a "reasonable basis" for their claims. FTC denied that the government has this responsibility and offered no evidence other than asserting that Petitioners lacked double-blind, placebo-controlled, clinical studies. Second, Petitioners argue, supported by their experts, that they did have competent and reliable scientific evidence, recognized in herbal medicine circles around the world, to support their claims.

According to the FTC, since Petitioners did not meet the government's "reasonable basis" standard of double-blind, placebo-controlled, clinical studies,

they are not entitled to the First Amendment protection afforded commercial speech. FTC Initial Decision, pp. 115-16. By so ruling, the FTC erroneously shifted to Petitioners the burden of proving that the First Amendment applied to their health claims and adopted the position that the Constitution permitted the FTC to prohibit Petitioners from making truthful statements about the relationship between their herbal supplements and specific health conditions.

The government has the burden of proof that Petitioners marketing claims are misleading. *Ibanez*, 512 U.S. at 138-39; *Peel*, 496 U.S. at 100-01; *In re RMJ*, 455 U.S. at 202-03. As noted above, the FTC ignored these cases as inapplicable. Relying on all three cases, the *Pearson* court rejected the FDA's effort to shift the burden of proof from the regulators to the marketer of dietary supplements to show that its claims were not "unscientific," and thus, not "inherently misleading." *Pearson*, 164 F.3d at 655. By refusing to apply *Ibanez*, *Peel*, and *In re RMJ*, the FTC and the court that affirmed its decision committed reversible error by failing to apply to Petitioner's health claims the First Amendment test set forth in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n. of New York*, 447 U.S. 557 (1980), discussed below.

In a third case, *Thompson v. Western States Medical Center*, 535 U.S. 357, 367-377 (2002), addressing drug compounding, a process by which a pharmacist or doctor combines, mixes, or alters

ingredients to create a medication tailored to an individual patient's needs, which is at least as, if not more, complex then choosing to use herbal supplements, this court explicitly held that commercial speech receives First Amendment protection, and "explained the reasons for this protection" as follows:

> It is a matter of public interest that [economic] decisions, in the aggregate, be intelligent and well-informed. To this end the free flow of commercial information is indispensable.... Indeed, we recognized that a particular consumer's interest in the free flow of commercial information ... may be as keen, if not keener, by far, than his interest in the day's most urgent political debate. *Thompson*, pp. 366-67.

> Additionally, the court "emphasized":
> The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented. Thus, even a communication that does no more than propose a commercial transaction is

entitled to coverage of the First Amendment. *Thompson*, p. 367.

The record shows that Petitioners' statements fall squarely within this court's First Amendment umbrella. The people seeking out Petitioners' information are looking for natural, non intrusive approaches to address their life situations. The information they receive is, according to the experts Petitioners called to testify, supported by "competent and reliable scientific evidence." The FTC, supported by the court below, seeks to block consumer access to this information as unprotected commercial speech.

In recognition of the First Amendment commitment to keep the channels of communication open, this court has imposed strict rules designed to limit government efforts to close them off, insisting that any such regulation must "directly advance" a "substantial government interest" by a regulation that is "not more extensive than is necessary to serve that interest." *Thompson*, p. 367. This case offers the court the opportunity to determine whether requiring double blind, placebo controlled clinical studies to support health claims for herbal supplements unnecessarily burdens the consumer's right to hear and the producer's right to speak. *Amici* urge the court to take this opportunity.

B. The First Amendment Standards Set Out By This Court Support Petitioners' Rights To Protected Speech.

The FTC, supported by the court below, misinterpreted and misapplied the U.S. Supreme court holding in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980), concerning the regulation of commercial speech. To understand their error, a review of constitutional analysis arising from *Central Hudson* is in order. *Amici* urge this court to accept the petition seeking review of this case to determine if the Commercial Speech tests set out by this court have been properly applied by the FTC. *Amici* believe they have not for the following reason.

In 1995, this court restated its *Central Hudson* formula, asserting that "the government may freely regulate commercial speech that ... is misleading," but established conditions for doing so *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 623-24 (1995). By means of this statement, the court confirmed that the threshold burden for regulating commercial speech is the government's, to show that statements in question are misleading, rather than the semantic shift in burden that results from requiring a commercial statement to be non-misleading. Highlighting this clarification, the court conformed its statement of the *Central Hudson* rule to the several court decisions that it had handed down in the 15 previous years since *Central Hudson* had been decided.

For instance, in 1982, the court, applying *Central Hudson*, ruled that a particular attorney

advertisement could not be "prohibited entirely," there being nothing in the record to show that the ad was either "inherently likely to deceive" or that the ad "has in fact been deceptive." *In the Matter of R. M. J.*, 455 U.S. 191, 202 (1982).

Then, in 1990, the court conferred First Amendment protection on another attorney promotional statement, on grounds that refute the FTC's position in this case. It said:

> (a) "[t]here is no contention that any client or person was actually misled or deceived by Petitioner's stationery;" nor
>
> (b) "any factual finding of actual deception or misunderstanding"; but only
>
> (c) a "conclu[sion], as a matter of law, that Petitioner's claims ... were necessarily misleading."
> *Peel*, 496 U.S. 91 100-01 (1990).

Thus, the *Peel* court concluded that, "[g]iven the complete absence of any evidence of deception in the present case, we must reject the contention that Petitioner's letterhead is actually misleading." *Id.*, 496 U.S. at 106. What the court prohibited in *Peel* is exactly what the FTC is doing in this case.

Four years later, in 1994, this court restated the *Central Hudson* rule and its rationale, as follows:

> Because disclosure of truthful, relevant information is more likely to make a positive contribution to decision making than its concealment of such information, ..., **only false, deceptive, or misleading commercial speech may be banned** .... *Ibanez*, 512 U.S. 136, 142 (1994). [emphasis added]

Thus, the *Ibanez* court ruled in favor of yet another attorney ad where "[t]he record reveals that the Board [of Accountancy] has not shouldered the burden that it must carry in matters of this order:"

> It has **not demonstrated** with sufficient specificity that any member of the public could have been misled by Ibanez' constitutionally protected speech or that any harm could have resulted from allowing that speech to reach the public's eyes. *Ibanez*, 512 U.S. at 138-39 [emphasis added].

Petitioners did not stand idly by in their relationship with the people who used their herbs. Rather they provided information to help their followers make better decisions. Complaint Counsel asserts, but offers no evidence, that since the information provided by Petitioners was not based on double-blind, placebo-controlled clinical studies it was inherently misleading. Nor did FTC cite any evidence that suppressing Petitioners' claims

"directly advances" a "substantial government interest" by a regulation that is "not more extensive than is necessary to serve that interest." *Thompson*, 535 U.S. at 367.

Not only must the government agency that seeks to suppress commercial speech meet its burden to prove the commercial speech at issue to be false, misleading or deceptive, as a matter of fact, but it must also "show that the restriction directly and materially advances a substantial state interest in a manner no more extensive than necessary to serve that interest." *Ibanez*, 512 U.S. at 142. Again, as the *Ibanez* court emphasized, "[t]he State's burden is not slight; the free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful." *Ibanez.*, 512 U.S. at 143.

In *Edenfield v. Fane*, 507 U.S. 761 (1995), the court explained that the government's "burden is not satisfied by mere speculation or conjecture," but only by "demonstrat[ing] that the harms [the government] recites are real and that restriction will in fact alleviate them to a material degree." *Edenfield*, 507 U.S. at 770-71. This requires actual, extrinsic evidence – not presumption.

Later that same year, in *Rubin v. Coors Brewery Co.*, 514 U.S. 476, 487 (1995), the court further stressed that unless this "critical" requirement is met, "a State could with ease restrict

commercial speech in the service of ... objectives that could not themselves justify a burden on commercial speech." *Edenfield*, 507 U.S. at 771.

In sum, a long line of Supreme court cases has demonstrated the requirement that "the Government bears the burden of **identifying** a substantial interest and **justifying** the challenged restriction." *Greater New Orleans Broadcasting Ass'n, Inc. v. United States*, 527 U.S. 173, 183 (1999) (emphasis added). *Thompson v. Western States Medical Center*, 535 U.S. 357, 367-377 (2002). *Amici* believe that the FTC is wrong in concluding that it has met this burden and urges the court to accept this petition to finally complete the task of guiding lower courts and regulators on how to address conflicts such as these.

CONCLUSION

Petitioners raise issues about the right to speak and the right to hear unorthodox health information that is supported by "competent and reliable scientific evidence," other than prohibitively costly double blind placebo controlled clinical trials. The area of discourse about such health claims is replete with conflict across the society. *Amici* believe that if this court accepts Petitioners' petition it will be able to effectively bring to a close the national contentious debate about protection of commercial speech that affects herbal and dietary health products.

For the foregoing reasons, *Amici* urge the court to grant the petition.

Respectfully submitted,

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IN THE

Supreme Court of the United States

DANIEL CHAPTER ONE, ET AL.,
Petitioners,
v.
FEDERAL TRADE COMMISSION,
Respondent.

On Petition for Writ of Certiorari
to the United States Court of Appeals
for the District of Columbia Circuit

BRIEF *AMICUS CURIAE* OF U.S. JUSTICE FOUNDATION AND CONSERVATIVE LEGAL DEFENSE AND EDUCATION FUND IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*[1]

The two *amici curiae* are legal defense organizations exempt from federal income taxation under IRC section 501(c)(3).

United States Justice Foundation ("USJF") (http://usjf.net/) was incorporated in California in 1979, and operates as a public interest law firm with interest in a wide range of issues. Since its founding, USJF has been involved in the protection of the First Amendment rights of individuals and entities, and, in that vein, has participated in many cases of note, including this one.

Conservative Legal Defense and Education Fund, ("CLDEF") (http://www.cldef.org) was incorporated in the District of Columbia in 1982, and operates as a legal defense organization dedicated to the correct construction, interpretation, and application of the law, and proper application of Biblical principles.

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[1] It is hereby certified that the parties have consented to the filing of this brief; that counsel of record for all parties received notice at least 10 days prior to the due date of the intention to file this *amicus curiae* brief; and that no counsel for a party authored this brief in whole or in part, and no person other than *amici curiae*, their members, or their counsel made a monetary contribution to its preparation or submission. The law firm of William J. Olson, P.C., attorneys for these *amici*, previously represented Petitioners, *inter alia*, in the U.S. Court of Appeals for the District of Columbia Circuit below, and in the U.S. District Court for the District of Columbia. Final substitution of counsel occurred on January 2, 2011.

STATEMENT OF THE CASE

Daniel Chapter One ("DCO") is a Christian house church which operates a healthcare ministry based on the spiritual gifts, education, training, and experience of its founders, James and Patricia Feijo. Structured as a nonprofit religious corporation sole under the laws of the State of Washington, and headquartered in Portsmouth, Rhode Island, DCO has presented the Gospel of Jesus Christ, taught Biblical principles of healthcare and healing from the Word of God, and offered a number of herbal and nutritional products for sale to the public for many years. DCO uses the Internet, publications, speaking engagements around the country, and a daily radio show to share the Good News of Jesus Christ and the healing qualities of DCO products. *See* Brief of Petitioners, Daniel Chapter One v. FTC, No. 10-1064 (D.C. Cir., Aug. 18, 2010) (hereinafter "Pet. Brief below"), pp. 7-12.

The products offered by DCO have included conventional herbal remedies, as well as a number of products that it developed according to Scriptural principles, and its study of the combined legacy of 6,000 years of the use of herbs and nutrition, as well as its observation of many persons who had personal experience in using those products. DCO's products have been remarkably effective in promoting the health of Christians and non-Christians alike across the country. These products help the body rid itself of toxins and pathogens, and provide it with the nutritional components which the body requires to fight off disease. All of these products help the body strengthen its immune system to do what it was

designed to do by God — to heal itself.[2] http://www.danielchapterone.com.

In the fall of 2008, however, DCO came under attack by the federal government for offering to the public these Scripturally-based and historically-proven dietary supplements as an alternative to "conventional" medicine — such as chemotherapy and radiation oncology. *See* Pet. Brief below, p. 15. This attack was launched by the Federal Trade Commission ("FTC"), in conjunction with the Food and Drug Administration ("FDA"), with the effect of serving the interests of the wealthy and powerful pharmaceutical industry, and the establishment medical community, by impeding the increasing use of alternative medicine by Americans. The FTC's usurpation to set the nation's health policy to limit patient choice was called "**Operation False Cures**." http://www.ftc.gov/opa/2008/09/ boguscures.shtm. As discussed below, thus far the FTC has never even attempted to prove the DCO product claims were actually false, nor is there any such proof.

The FTC developed a theory that DCO was misleading the public solely because DCO had not tested any of its **natural dietary supplements** by controlled clinical studies of the kind conducted by the FDA before permitting the marketing of a **toxic**

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[2] One of the remarkable stories of the benefits of DCO testimony was submitted below by Declaration. See Declaration of Tedd Koren, D.C., U.S. Court of Appeals. http://www.lawandfreedom.com/site/health/DCOdeclarations/Mem_Opp_PI/Exh4_Koren.pdf

pharmaceutical drug. The FTC ignored DCO's contentions that: (a) there is **no health or safety reason** to test a nutritional supplement as one would a toxic pharmaceutical drug, and (b) most food supplements cannot be patented because it is **financially impossible** to meet the test established by the FTC. DCO made no claim that its products were backed by FDA-style tests. Rather DCO promoted its products primarily on the basis of testimonies of persons who had benefitted from using those products in their fight against cancer. In fact, the FTC was **unable to find even one person to testify** that he had been led to think that DCO's product claims were based on FDA-style clinical studies. And, despite the devotion of enormous government resources in the effort to silence DCO's educational efforts about its products, the FTC was **unable to find even one person who was harmed** by them. *See* Pet. Brief below, pp. 16, 28-29.

On the other hand, DCO brought many lay witnesses to testify under oath as to the safety and efficacy of DCO products. The **FTC's Chief Administrative Law Judge ("ALJ")** upheld the position of the FTC Complaint Counsel, and shut his ears to these lay witnesses — keeping them from testifying about their personal experiences of healing with DCO products.

The ALJ did allow DCO to present four expert witnesses, including a renowned herbalist and a naturopath, to testify, but immediately discounted all of their testimony for the sole reason that they were not medical doctors. Instead, the FTC relied

exclusively on the testimony of **one medical doctor** who no longer practices medicine, but works as a professional expert witness and designs drug studies for the same pharmaceutical industry being criticized by DCO. This same so-called expert witness could not even answer the ALJ's question as to whether an herb was a plant. *See* Pet. Brief below, pp. 29-30.

In its Petition for Review, DCO waged a vigorous challenge to the FTC's claim that it had the authority: (i) to require DCO to conform its dietary supplement ads to the FDA's "scientific" standards governing pharmaceutical drugs, and (ii) to impose its view of "scientific truth" upon DCO. DCO's petition, however, was summarily denied, without published opinion.

SUMMARY OF ARGUMENT

The FTC applied an erroneous legal standard, exercising jurisdiction over a religious ministry on the sole ground of the mere receipt of income, rather than upon the statutory requirement that such income be in excess of that which is required to carry out the ministry's nonprofit activities. Such a fundamental error intruding upon a nonprofit religious organization should not go uncorrected.

The FTC also applied an erroneous standard claiming that the ministry's marketing of dietary supplements was deceptive on the sole ground that the health claims made on their behalf did not meet FDA's standard of "controlled clinical studies" required of toxic pharmaceuticals, not because the claims were, in fact, false, as required by the FTC Act. Such a

fundamental error of statutory interpretation should be reversed.

Lastly, the FTC has done what no government has authority to do — to make the health care choices for competent individuals, over their objection. And, in ordering DCO to convey the FTC's healthcare views, DCO's First Amendment right to "speaker autonomy" and the protections afforded it by the Religious Freedom Restoration Act were ignored, constituting fundamental errors overlooked by the court of appeals, and warranting this court's review.

ARGUMENT

I. THE FTC CLAIM OF JURISDICTION OVER CHURCHES AND NONPROFIT RELIGIOUS AND MINISTRIES IS AN IMPORTANT ISSUE OF FEDERAL LAW MERITING REVIEW BY THIS COURT.

A. The Court of Appeals Erroneously Allowed the FTC to Assert Jurisdiction over Daniel Chapter One.

The Petitioners assert that the "decision below is the first time in which the court of appeals has held that a church or religious ministry is within the jurisdiction of the FTC..." and that the "D.C. Circuit's holding expands the jurisdiction of the FTC Act beyond what is allowed under the statute and the First Amendment's protection of the free exercise of religion." Pet., pp. 8, 10. These *amici* believe these representations are completely correct, and that the

Petition establishes that the court of appeals "has so far departed from the accepted and usual course of judicial proceedings ... as to call for an exercise of this Court's supervisory power...." Supreme Court Rule 10(a).

The FTC "has only such jurisdiction as Congress conferred upon it." Community Blood Bank v. FTC, 405 F.2d 1011, 1015 (8th Cir. 1969). "[I]f the jurisdiction of the Commission is challenged, it bears the burden of establishing its jurisdiction." *Id.*

The current assertion of FTC jurisdiction did not go unchallenged by DCO. Both at the hearing before the FTC, and on appeal, DCO challenged the jurisdiction of the FTC on the ground that DCO is **not** a corporation that is "organized to carry on business **for its own profit or that of its members**" — within the meaning of 15 U.S.C. section 44 (emphasis added). The FTC erred, *inter alia*, by applying an erroneous legal standard to the question of jurisdiction, having misapplied the rule of Community Blood Bank. Yet the court of appeals, without taking the care to issue a published opinion, decided this important issue affirming the FTC's usurpation of authority.

1. The FTC Applied an Erroneous Legal Standard.

The FTC found that DCO had been "organized" as a nonprofit corporation sole since 2002, having been so incorporated under the laws of Washington state. ALJ

Dec., Findings of Fact ("FoF") 28; A-174[3]; Comm. Op., p. 4, A-302. According to Washington state law, a corporation sole, by definition, is a church or religious society organized by a single overseer with the duty of holding all corporate property in "trust for the use, purpose, benefit, and behoof of his religious denomination, society or church." *See* RCW §§ 24-12.010 -24.12.030. Many church organizations are organized as a corporation sole, particularly Roman Catholic Dioceses under the authority of a local bishop. J. O'Hara, "The Modern Corporation Sole," 93 *Dickinson L. Rev.* 23, 33, 35 (1988). Article 3 of DCO's Articles of Incorporation dedicates DCO "to do whatever will promote the Kingdom of God," including "educating people in the fundamentals of liberty." ALJ Dec., FoF 29; A-175.

Yet, in an effort to circumvent DCO's express Christian purpose,[4] as well as the statutory constraints of Washington state law, the FTC erroneously asserted that "DCO bears **none** of the substantive indicia of a corporation that is truly organized **only for charitable purposes.**" ALJ Dec., p. 71, A-237; Comm. Op., p. 8, A-306 (emphasis added). Under the FTC Act, it is the FTC's burden to establish that DCO has been "organized to carry on business for its own profit," not DCO's burden to prove otherwise.

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[3] References to "A" are to the Appendix filed with the briefs in the court of appeals.

[4] *See* Matthew 6:33; Mark 1:14; Luke 4:4, John 3:3, and Acts 1:3.

2. The FTC Erroneously Assumed that DCO's Receipt of Income Established FTC Jurisdiction.

Purporting to apply the rule in Community Blood Bank, the FTC erroneously ruled that DCO was subject to FTC jurisdiction because "by engaging in commercial activities, DCO operates a commercial enterprise," not a religious or charitable ministry. *See* Comm. Op., p. 7, A-305. No such dichotomy exists. Under Washington law, a corporation sole is authorized to "transact[] business" without negating or violating the corporation's charitable purpose. *See* In re Catholic Bishop of Spokane, 329 Bankr. Rep. 304, 327-28 (E.D. Wash. 2005). Indeed, the history and modern use of the corporation sole form strongly establish their essential "ecclesiastical" nature and purpose, while at the same time engaging in supportive commercial activities. *See* O'Hara, "The Modern Corporation Sole," at 33, 35 (1988).

The FTC incorrectly presumed otherwise — that DCO was a corporation organized **for profit** simply because DCO was engaged in money-generating sales of its products. *See* Comm. Op., pp. 4-8, A-304-07. That was the same error that the FTC made in Community Blood Bank, wherein the FTC claimed jurisdiction over a "corporation engaged in business only for charitable purposes [if it] receives income in excess of expenses." *See id.*, 405 F.2d at 1016. However, Community Blood Bank expressly rejected that argument, ruling that "even though a corporation's income exceeds its disbursements its nonprofit character is not necessarily destroyed." *Id.*,

405 F.2d at 1017. Instead, the court adopted the rule that an entity's nonprofit character is lost **only if it can be shown that** either the entity or its members "derived a profit **over and above** the ability to **perpetuate or maintain** [its] existence." *Id.*, 405 F.2d at 1019 (emphasis added). DCO "'does not cease to be a nonprofit corporation merely because it has income.'" *See id.*, 405 F.2d at 1020.

II. THE FTC MISUSE OF ITS STATUTORY AUTHORITY IS AN IMPORTANT ISSUE OF FEDERAL LAW MERITING REVIEW BY THIS COURT.

Sections 5(a) and 12 of the FTC Act (15 U.S.C. §§ 45(a) and 52), respectively, make unlawful "deceptive acts or practices" and "false" advertisements "in or affecting commerce." The FTC believes that it may enforce these prohibitions under either its (i) "'falsity' theory" or (ii) "'reasonable-basis' theory." *See* ALJ Dec., p. 99, A-265. Tracking the statutory language, the falsity theory appropriately requires "the government [to] carry the burden of proving that the express or implied message conveyed by the ad is false." *Id.*, n.4, A-265. Under its "reasonable basis" construct, however, the FTC circumvents the FTC Act's requirement that it prove deception or falsity, as the FTC claims that it need only establish that an ad's "**net overall impression**" "carr[ied] ... the express or implied representation that the advertiser had a **reasonable basis** substantiating the claims at the time the claims were made." *Id.* at 99, A-266 (emphasis added). Once this foundation has been established, then the burden shifts to the advertiser to

produce the "substantiation they relied on for their product claim," after which the FTC has "the burden of establishing that [the] purported substantiation is inadequate." *Id.* at 100, A-266.

Moreover, in this case, the FTC has manipulated its reasonable basis theory to require DCO not just to substantiate that its implied product claims are "reasonable," but also that its implied claims are supported by "competent and reliable scientific evidence," that is , by the FDA standard of "controlled clinical studies." *See* ALJ Dec., pp. 103-04, A-269-70. The FTC has imposed this burden on DCO without first establishing the factual predicate required by its "reasonable basis" theory, namely, that the "overall net impression" of DCO's ads carried the express or implied representation that DCO's product claims were based on such "controlled clinical studies." Because the FTC has bypassed this step, it has misused its own "reasonable basis" theory to further a public health policy unauthorized by the FTC Act, and thereby, has exercised a power **not** conferred by Congress as unambiguously stated in sections 5(a) and 12 of the FTC Act, and as reinforced by the Dietary Supplement Health and Education Act of 1994.

Because the language of sections 5(a) and 12 unquestionably limit the FTC's authority to protecting the consumer from "fraud, deception, and unfair business practices in the marketplace,"[5] the standard of review governing the FTC's authority in this case is

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[5] Federal Trade Commission, "Protecting America's Consumers" http://www.ftc.gov.bcp/index.shtml.

not governed by the principle of deference to a reasonable administrative interpretation of the empowering statute, but by *de novo* review in the Court of Appeals, as well as by this Court. *See* General Dynamics Land Systems, Inc. v. Cline, 540 U.S. 581, 600 (2004).

A. Requiring DCO to Substantiate Its Product Claims by "Controlled Clinical Studies" Is outside FTC's Statutory Authority.

The FTC never claimed that DCO actually made any false representation respecting any of the Four Challenged Products. *See* ALJ Dec., p. 99, A-265; Comm. Op., p. 12, A-310. Rather, the FTC alleged that DCO's statements about the Four Challenged Products created the **overall net impression** that (i) each product was effective in the treatment of cancer or inhibited or eliminated tumor growth, and (ii) that DCO implied that it possessed and relied upon a **reasonable basis** that substantiated that overall net impression. *See* Compl. ¶¶ 6-15, A-24-27 (emphasis added). Alleging further that DCO's claims were, in fact, unsubstantiated by any "reasonable basis," the FTC charged DCO with having engaged in "unfair or deceptive acts or practices, in or affecting commerce in violation of Sections 5(a) and 12 of the FTC Act." Compl. ¶ 17, A-27.

At the hearing, DCO presented evidence through five expert witnesses. Yet, the ALJ entirely disregarded their opinions because they did not address whether "there is **competent and reliable scientific evidence**" to support DCO's claims about

the efficacy of the Four Challenged Products. *See* ALJ Dec., FoF 388-89, 398-400; A-227-29 (emphasis added). However, the FTC Complaint did not charge DCO with having implied that its claims were based upon "competent and scientific evidence"; it charged only that DCO's ads implied that it had a "reasonable basis" for its claims. Compl. ¶¶ 14-15, A-27. Nor did the ALJ require that the FTC establish that DCO's advertisements implied that its product claims rested on "competent and reliable scientific evidence," as the reasonable basis theory purports to require. Instead, the ALJ ruled that a general standard of "reasonableness" did not apply, because DCO's statements were "health-related" and, for that reason alone, they "require[d] a high level of substantiation" — which the ALJ determined to be "competent and reliable scientific evidence." *See* ALJ Dec., p. 102, A-268.

Indeed, the ALJ — not finished in raising the bar — then ruled that DCO's health-related claims must meet an even higher standard of substantiation. Because DCO's claims gave the overall net impression "that the Challenged Products prevent, treat or cure cancer, inhibit tumors, and ameliorate the adverse effects of radiation and chemotherapy," the ALJ insisted that DCO must show that its claims were supported by "**controlled clinical studies**" of the kind required by the FDA for the approval of a new pharmaceutical drug. *See* ALJ Dec., p. 103, A-269. *See also* Expert Report of Denis R. Miller, M.D. ("Miller Report"), pp. 7-12, A-76-81. Again, the ALJ did not require FTC to establish that the net overall impression of DCO's claims implied that they rested on such "controlled

clinical studies," as the "reasonable basis" theory purports to require. Instead, the ALJ justified the higher standard of "controlled clinical studies" on the ground that "the evidence shows that foregoing a proven cancer treatment in favor of an ineffective treatment would be injurious to a patient's health." ALJ Dec., p. 103, A-269.

On administrative appeal, the Commission affirmed, ruling that DCO has "not produced anything to show that they possessed and relied on any competent and reliable scientific evidence to support the overall net impressions conveyed by the advertisements at issue." Comm. Op., p. 18, A-316. The Commission agreed with the ALJ that only the FTC witness — a medical doctor and oncologist — was qualified to testify as to whether there was a "reasonable basis" for DCO's claims, and adopted, as its own, the FTC witness' definition of "competent and reliable scientific evidence." Comm. Op., pp. 18, 22, A-316, A-320. As stated in his report, the FTC expert witness explained that:

> to **constitute competent and reliable scientific evidence**, a product that purports to treat, cure, or prevent cancer must have **efficacy and safety demonstrated through controlled clinical studies**. **My understanding** of what constitutes competent and reliable scientific evidence is **consistent with the FDA's regulations** that define the criteria for adequate and well-controlled clinical investigations, which are set forth at 21 C.F.R.

> sec. 314.126. [Miller Report, pp. 7-8, A-76-77 (emphasis added).]

The criteria set forth in the cited Code of Federal Regulations section is the standard promulgated by the FDA governing approval to market a new pharmaceutical drug, a matter totally outside the authority of the FTC. Yet, Dr. Miller applied, and the FTC erroneously adopted, that FDA pharmaceutical standard to determine whether DCO had engaged in a "deceptive act or practice" under section 5(a) of the FTC Act with respect to a dietary supplement, as if the FTC, like the FDA, were empowered by statute to protect the public health and safety.

The FTC is "charged with the enforcement of no policy except the policy of the law." *See* Humphrey's Executor v. United States, 295 U.S. 602, 624 (1935). On their face, sections 5(a) and 12 of the FTC Act authorize the FTC **only** to protect consumers from deceptive or misleading advertising, **not** to protect the public health and safety — areas in which the FTC commissioners have no education or expertise.

III. THE COURT OF APPEALS' REJECTIONS OF DCO'S RELIGIOUS FREEDOM RESTORATION ACT AND FIRST AMENDMENT "SPEAKER AUTONOMY" CLAIMS CONSTITUTE FUNDAMENTAL ERRORS WARRANTING THIS COURT'S REVIEW.

A. No Government Has Authority to Dictate the Health Care Choices of Competent Individuals.

As discussed in Section I of this Argument, *supra*, the FTC has no jurisdiction over DCO because the U.S. Congress has given it no power to regulate statements made by religious ministries and churches. And, as discussed in Section II, *supra*, the FTC has no authority to require that DCO substantiate its opinions about nutritional supplements with clinical tests of the sort required for toxic drugs.

However, even more insidious is the court of appeals' affirmance of the FTC's assumption of a power that the federal government does not have over the sovereign people in this constitutional republic.

A government's basic function is established in I Peter 2:11-13: "Submit yourself ... unto governors, as unto them that are sent by him for the **punishment** of **evildoers**, and for the **praise** of them that **do well**." While the FTC, no doubt, believes that it is doing well, it is not the government that decides what is good and what is evil — but God, as revealed in Holy Scriptures.

Indeed, perverting the legitimate function of government, the FTC's actions benefit those who seek to force Americans away from using health-giving herbal and other nutritional supplements and rely exclusively upon toxic drugs marketed by powerful pharmaceutical interests. At the same time, the FTC punishes those like DCO who are doing good — warning the nation of evil in a watchman's ministry (Ezekiel 3:17), educating and exhorting the Church to an understanding of the body as God designed it, and providing a healing ministry offering products to the Church and beyond.[6]

In seeking to know the mind of God on the topic of evil in healthcare, increasing numbers of Christians find it instructive that the Greek word "pharmakeia" (Strong's G5331) — which is the root of "pharmaceutical" — is translated in the Holy Bible as "witchcraft" (Galatians 5:20) and "sorceries" (Revelation 9:21; Revelation 18:23 "for by their sorceries were all nations deceived.").

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[6] The Petition for Certiorari sets out the issues presented in terms of the right of "parishioners" to purchase DCO products. This terminology is commonly applied to today's "local churches," and "house churches" where the First Century Church met (*see, e.g.*, 1 Corinthians 4:17; 2 Corinthians 11:8; 1 Thessalonians 2:14; 2 Thessalonians 1:1. However DCO's ministry is not so limited, but rather directed to what is known as the "church universal" (*see, e.g.*, Matthew 16:18; Ephesians 1:22-23; 1 Corinthians 12:28; *see also* Nicene Creed (reference to "one holy catholic and apostolic Church")). In fact, like Jesus' healing ministry, DCO's ministry is not confined to those already believers (*e.g.*, Luke 6:6-11), but rather serves as a means to draw people to Christ, *i.e.*, to proselytize.

The human body may be matter in motion to an atheist, but to the Christian, it is the "Temple of the Holy Spirit." 1 Corinthians 6:19. The body, then, is to be treated in accord with Biblical principles. I Corinthians 6:20. While a medical doctor who rejects the Bible may view himself as the source of life for the sick, a Christian knows that God is the giver and author of life. *See* Genesis 1 and 2; Acts 3:15. The medical doctor exclusively relied on by the FTC's Administrative Law Judge is an advisor to the sick — not a decider for the sick. The FTC ignored this truth. The court of appeals did not even believe these foundational principles deserved to be addressed in a published opinion.

The FDA may believe that most medical problems can be cured with toxic pharmaceuticals, but Christians increasingly understand that, while science can replicate certain substances which cannot be produced physiologically in certain persons, there are no illnesses caused by a deficiency of a pharmaceutical drug.

There is no command in Scripture that deals with the body that identifies any role for the government, yet the FTC claims a role that God gave to each person, individually. In the first chapter of the book of Daniel, after which DCO takes its name, Daniel was willing to risk his life to obey God's dietary instructions. *See* Daniel 1:10-16. It is no coincidence that, while over 100 other organizations threatened by the FTC capitulated, that the one organization still resisting evil is a small religious ministry from the

smallest state in the nation, standing against governmental wrongdoing. *See* Ephesians 6:14.

B. Parts II and III of the FTC's Order Substantially Burden DCO's Exercise of Religion in Violation of RFRA.

The court of appeals dismissed Petitioners' Religious Freedom Restoration Act, 42 U.S.C. §§ 2000bb-1(a), *et seq.*, ("RFRA") claim by simply declaring that "neither evidence nor logic supports DCO's argument that religious tenets prevented sending its customers a letter with a message clearly attributed to the FTC." Per Curiam Judgment ("Judg.), p. 2. This ruling highlights the consistent failure of the FTC and the court of appeals to attribute any worth to DCO's religious beliefs, not even purporting to address, certain "exercise of religion" claims made by the Petitioners. The ruling below is an attempt to circumvent the requirements of RFRA itself. *See* Gonzales v. O Centro Espirita Beneficente Uniao Do Vegetal, 546 U.S. 418, 434 (2006).

As Petitioners argued below, by requiring DCO to possess and rely upon competent and reliable scientific evidence with respect to any health claims, the Order substantially burdens DCO's "exercise of religion," which includes "any exercise of religion, whether or not compelled by, or central to, a system of religious belief." 42 U.S.C. §§ 2000bb-2, 2000cc-5. *See* Pet. Brief below, pp. 55-60.

The Christian faith, in particular, teaches the interrelation between a person's spiritual and physical

health, with an emphasis upon the Biblical principle that God is the source not only of the salvation of man's soul but the healing of man's body. *See* Isaiah 53:5 and 1 Peter 2:24. That principle lay at the heart of the DCO ministry, as reflected in its very name and its operation. Enforcement of Parts II and III of the Order would require DCO to change its allegiance from God and the Bible to "the expertise of professionals in the relevant area," as determined by the FTC. *See* Modified Final Order, Part I.A, p. 1, A-334. Instead of relying on prayer, testimony, and the application of Biblical principles, DCO would be required to "possess and rely" on "tests, analyses, research, or other evidence ... that has been ... conducted and evaluated in an objective manner by persons qualified to do so," as determined by the FTC. *Id.* Such an order would effectively destroy the integrity of the DCO ministry, even if its claims for the products covered by Parts II and III are otherwise, in fact, "true and nonmisleading." *See* Pet. Brief below, pp. 58-60. Indeed, as Petitioners argued below, the Order would require DCO to embrace the FTC's **secular belief** that conventional cancer treatments have been "**scientifically proven,**" directly contrary to DCO's deeply held religious beliefs, laying the foundation for one of Petitioners' claims under RFRA. *See* Pet. Brief below, p. 60. The court of appeals did not address these arguments, effectively ignoring the protections afforded by RFRA for those exercising their religion.

C. Part V.B of the FTC's Order Contravenes both RFRA and the First Amendment Principle of Speaker Autonomy.

According to RFRA, the Order cannot substantially burden **any** "exercise of religion," whether compelled by or central to a system of religious belief. 42 U.S.C. § 2000cc-5(7). According to the Supreme Court, exercise of religion is not limited to the positive expression of "belief and profession," but includes "abstention from physical acts." *See* Employment Division, Dept. of Human Resources v. Smith, 494 U.S. 872, 877 (1990).

By requiring DCO to sign and mail a letter containing the views of the FTC, thereby forcing DCO to identify itself with a message with which it profoundly disagrees, the Order substantially burdens DCO's exercise of religion. The court of appeals, without analysis, summarily dismissed DCO's RFRA and First Amendment claims as nothing more than deceptive commercial speech. *See* Judg., p. 2. In either event, it erred, in violation of RFRA. Aside from the fact that Petitioners were never permitted to pursue their RFRA claim below — so that the court of appeals had no record on which to discern the tenets or practices of DCO's religion — the court of appeals mischaracterized the Order, which does much more than send a message that may be attributed to the FTC.

Indeed, an entire paragraph of the Order is devoted to **counseling** in connection with **herbal products generally**, telling the recipient, first, that "it is

important to **talk to your doctor or health care** provider before using **any** herbal product in order to ensure that all aspects of your medical treatment work together." Order, Att. A, p. A-340. Next, the recipient is advised that "[s]ome **herbal products** may interfere or affect your cancer or other medical treatment, may keep your medicines from doing what they are supposed to do, or could be harmful when taken with other medicines, or in high doses." *Id.* Finally, the recipient is counseled "to talk to your doctor or health care provider before you decide to take **any herbal product** instead of taking **cancer treatments** that have been **scientifically proven to be safe and effective** in humans."[7] *Id.* Clearly, the letter mandated by the Order would require DCO to embrace and propagate the FTC's **secular belief** that conventional cancer treatments have been "**scientifically proven,**" directly contrary to DCO's deeply held religious beliefs. *See* Pet. Brief below, p. 60.

By design, the FTC Order mandates that Petitioners not only use their private property to carry the FTC's message, but purport to be the FTC messengers, at risk of substantial penalties, including a "civil" sanction of up to $16,000 for each of the many

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[7] There is strong debate over the "effectiveness" of conventional cancer cures. For example, oncologist Guy B. Faguet, M.D.'s study of "three decades of disappointing progress in cancer treatment" concludes that "disease eradication is currently achievable in only 11 of over 200 human malignancies and meaningful survival prolongation is possible for another few...." Guy B. Faguet, The War on Cancer (Springer 2008), pp. xiii-xiv.

hundreds of letters unsent -- if they fail to do so. *See* 15 U.S.C. § 45(m). The First Amendment supports the Petitioners' belief and argument below that they should not be required to speak the FTC's own words in the FTC's stead, a principle which the Supreme Court stands firmly behind. *See, e.g.*, Hurley v. Irish-American Gay, Lesbian and Bisexual Group of Boston, 515 U.S. 557, 573 (1995); Wooley v. Maynard, 430 U.S. 705, 713 (1977).

The court of appeals never even mentioned the principle of speaker autonomy, or the Petitioners' First Amendment argument that the Order clearly violated that principle. In the context of dismissing Petitioners' RFRA claims, the court stated that the complained-of message was "clearly attributed to the FTC" (Judg., p. 3), but the only mention of the First Amendment was to declare that, even if it were to apply, the Order was "carefully tailored to protect DCO's clientele from deception." *Id.* at 2.

The court of appeals cannot be permitted to run roughshod over the rights of litigants, ignoring important pronouncements by this Court. In Wooley v. Maynard,, the petitioner filed an affidavit wherein he stated that he "refused to be coerced by the State into advertising a slogan which [he found] morally, ethically, religiously and politically abhorrent." *Id.*, 430 U.S. at 713. The Court ruled that government may not "require" persons to "use their private property ... for the State's ideological message — or suffer a penalty" for noncompliance. *Id.*, 430 U.S. at 715. In Pacific Gas and Electric Company v. California P.U.C., 475 U.S. 1 (1986), the Supreme Court ruled

that a state agency could not require a company to send a "billing envelope[] to distribute the message of another." *See id.*, 475 U.S. at 17.

Likewise, the FTC should not be allowed to force Petitioners to deliver the government's message with which they disagree: "For to compel a man to furnish contributions of money for the propagation of opinions with which he disagrees is sinful and tyrannical." Virginia Act for Establishing Religious Freedom (1785), reprinted in 5 The Founders Constitution 84 (P. Kurland & R. Lerner, eds.: Liberty Press: 1987). This principle of "speaker autonomy" — the right "to choose the content of his own message" — is a "fundamental rule of protection under the First Amendment." *See* Hurley v. Irish-American Gay, Lesbian and Bisexual Group of Boston, 515 U.S. at 573. In upholding the FTC Order, the court of appeals ignored that important principle, and its judgment should be reversed.

CONCLUSION

When DCO filed its Petition for Review with the United States Court of Appeals for the District of Columbia Circuit, it had hoped for an independent judicial review of the several claimed errors that it presented. Instead, the court of appeals summarily dismissed DCO's petition in a one-and-a-half page unpublished opinion in complete deference to the FTC — administrative agency wielding legislative, executive and judicial powers.

Our founders warned against concentrating all three powers in one government: "The accumulation of all powers ... in the same hands ... may justly be pronounced the very definition of tyranny." The Federalist No. 47 (James Madison). More than 370 years ago, the English Parliament abolished the Court of Star Chamber by an Act that restored to the people the right to have their causes "to be tried and determined in the ordinary courts of justice, and by the ordinary course of law." *See* Sources of Our Liberties, p. 149, R. Perry & J. Cooper, eds., ABA Found.: 1978). "The main effect, [then], of the abolition of the Star Chamber was to establish ... a system of justice administered by the courts instead of by the administrative agencies of the executive branch of the government. The statute thus constituted an important reaffirmation of the concept of due process of law..." *Id.* at 132. While this Court has no authority to abolish the FTC, it does have the power to grant the petition reviewing this matter and thereby affording Petitioners a reasonable measure of justice.

For the foregoing reasons, the petition for writ of certiorari should be granted.

Respectfully submitted,

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